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ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

#28 JANUARY 10, 2012

Sachi A. Hamai
SACHI A. HAMAI
EXECUTIVE OFFICER



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January 10, 2012

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**APPROVAL TO EXECUTE A SOLE SOURCE AGREEMENT WITH THE LOS ANGELES GAY
AND LESBIAN COMMUNITY SERVICES CENTER FOR THE PROVISION OF NON-
OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE PROPHYLAXIS
SERVICES EFFECTIVE UPON DATE OF BOARD APPROVAL THROUGH FEBRUARY 28, 2013
(ALL SUPERVISORIAL DISTRICTS) (3 VOTES)**

SUBJECT

Request approval to execute a sole source agreement with the Los Angeles Gay and Lesbian Community Services Center for the provision of non-occupational Human Immunodeficiency Virus post-exposure prophylaxis services to individuals in Los Angeles County who have had a high risk exposure to Human Immunodeficiency Virus within the previous 72 hours.

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of the Department of Public Health (DPH), or his designee, to execute a sole source agreement with the Los Angeles Gay and Lesbian Community Services Center (LAGLC), substantially similar to Exhibit I, to provide non-occupational Human Immunodeficiency Virus (HIV) post-exposure prophylaxis (nPEP) services, effective upon date of Board approval through February 28, 2013, at a total maximum obligation of \$558,318, 100 percent offset by the Centers for Disease Control and Prevention (CDC) Enhanced Comprehensive HIV Prevention Planning (ECHPP) funds.
2. Delegate authority to the Director of DPH, or his designee, to execute amendments to the LAGLC agreement that extend the term through February 28, 2014; allow for the rollover of unspent funds; adjust the term of the agreement through May 31, 2014; and/or provide an increase or a decrease in funding up to 25 percent above or below each term's annual base maximum obligation,

effective upon amendment execution or at the beginning of the applicable agreement term, subject to review and approval by County Counsel, and notification to your Board and the Chief Executive Office (CEO).

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of Recommendation 1 will allow DPH to execute a sole source agreement with the LAGLC to provide nPEP services including antiretroviral therapy and other appropriate HIV treatment to individuals who have had a high risk exposure to HIV to stem the incidence of HIV infections within Los Angeles County (LAC).

Under Recommendation 2, DPH is requesting delegated authority to execute amendments to increase and/or decrease funding up to 25 percent above or below the annual base maximum obligation, effective upon amendment execution or at the beginning of the applicable agreement term. This recommended action will enable DPH to amend agreements to adjust the term for a period of up to 15 months beyond the initial expiration date of February 28, 2013. Such amendments will only be executed if and when there is an unanticipated extension of the term of the applicable grant funding to allow additional time to complete services and utilize grant funding. This authority is being requested to enhance DPH's efforts to expeditiously maximize grant revenue, consistent with Board Policy 4.070: Full Utilization of Grant Funds.

Recommendation 2 will also enable DPH to amend the agreement to allow for the provision of additional units of funded services that are above the service level identified in the proposed agreement's scope of work and/or the inclusion of unreimbursed eligible costs, based on the availability of grant funds and grant funder approval. While the County is under no obligation to pay a contractor beyond what is identified in the original executed agreement, the County may determine that the contractor has provided evidence of eligible costs for qualifying contracted services and that it is in the County's best interest to increase the maximum contract obligation as a result of receipt of additional grant funds or a determination that funds should be reallocated. This recommendation has no impact on net County cost.

DPH proposes to provide nPEP services in LAC to avert new HIV infections among some of the highest risk clients by utilizing an innovative prevention/treatment intervention. The nPEP program is a biomedical component which provides a comprehensive set of treatment and prevention services to individuals who have had a non-occupational exposure to HIV within the previous 72 hours in an effort to stem the incidence of new HIV infections. It includes a month-long provision of antiretroviral therapy, therapeutic adherence counseling, and prevention interventions. Potential candidates for nPEP are thoroughly screened for existing HIV infection and other sexually transmitted diseases (STDs) and counseled on possible medication-related side effects and consequences of noncompliance with the medication regimen. Eligible patients must meet highly standardized screening criteria to receive nPEP services. nPEP can only be prescribed by HIV clinical services staff in a clinic setting. Clinical evaluation, antiretroviral therapy, and other appropriate HIV treatment monitoring is also conducted for these patients.

In 2005, the CDC recommended nPEP as an effective intervention strategy to prevent HIV infection. nPEP delivered preemptively to reduce HIV infection and transmission following a non-occupational sexual or injection-drug-use exposure can be beneficial. In addition to the CDC recommendations, the United States Department of Health and Human Services (DHHS) established a working group to evaluate nPEP effectiveness. As a result, the DHHS working group provided additional

recommendations to healthcare providers that persons should seek care within 72 hours after a high-risk exposure to potentially infectious body fluids, when that exposure represents a substantial risk for HIV transmission.

In 2008, LAC formed an nPEP workgroup comprised of members of the LAC HIV Prevention Planning Committee; LAC Commission on HIV; DPH representatives; University of California, Los Angeles researchers; State Office of Acquired Immune Deficiency Syndrome (AIDS) representatives; and community-based providers (i.e., AIDS Project Los Angeles, AIDS Healthcare Foundation, Women Alive, and the LAGLC). The purpose of the workgroup was to develop a protocol and implementation plan for viable nPEP demonstration sites, situated in high burden areas in LAC that serve a diverse population at increased risk for HIV exposure. The selected demonstration sites that met the criteria would participate in a clinical study to demonstrate the feasibility of delivering nPEP services in a community-based clinical setting to a diverse population at increased risk for HIV exposure, predominantly men who have sex with men. Based on the criteria outlined above, LAGLC was one of only two agencies in LAC qualified to participate in the nPEP clinical study, along with the Department of Health Services' OASIS Clinic (OASIS Clinic). DPH plans to continue nPEP services with the OASIS Clinic through a Departmental Service Order (DSO). At the conclusion of the clinical study, LAGLC demonstrated that they could deliver this complex intervention safely and effectively; a total of 255 patients successfully completed nPEP therapy and avoided HIV infection. There is a high morbidity of HIV/STD identified at the LAGLC health clinics, the Sexual Health Care Clinic and Jeffrey Goodman HIV Care Clinic, located in Service Planning Area 4. Upon Board approval, nPEP services will be offered through these high morbidity HIV/STD health clinics and available to all LAC residents in LAC who meet the eligibility criteria to receive nPEP services.

LAGLC's clinics serve some of the highest-risk populations in LAC, e.g., geographic area with the highest prevalence of HIV, and have a long history of providing culturally sensitive prevention and clinical care to racial, ethnic, and sexual minorities who are at extreme risk for acquiring HIV. In 2010, the LAGLC diagnosed over 293 new HIV cases (almost 30 percent of the estimated new HIV infections in LAC, and a 3.7 percent positivity rate), over 1,100 chlamydia cases, and over 1,400 gonorrhea cases. In over 300 of the chlamydia cases and 350 of the gonorrhea cases, co-infection of HIV was present. DPH recommends continued support of this intervention, through the proposed sole source agreement. Providing this prevention intervention through a community-based care setting is a remarkable and innovative strategy to help reduce HIV infection in LAC in high-risk areas.

Implementation of Strategic Plan Goals

The recommended actions support Goal 4, Health and Mental Health, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

The total maximum obligation for the LAGLC agreement, effective upon date of Board approval through February 28, 2013 is \$558,318, which consists of \$145,427 for the period effective upon date of Board Approval through February 29, 2012 and \$412,891 for the period March 1, 2012 through February 28, 2013; 100 percent offset by CDC ECHPP funds.

Funding is included in DPH's fiscal year (FY) 2011-12 Final Adopted Budget and will be requested in future FYs, as necessary.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

In March 2010, the CDC released a Request for Application (RFA) Number 10-10181 for ECHPP Phase I designed to assist local jurisdictions to apply federal HIV prevention strategies by supporting unmet HIV prevention needs. In June 2010, the DPH Division of HIV and STD Programs (DHSP), formerly the Office of AIDS Programs and Policy, submitted its application to the CDC and on September 29, 2010 DPH/DHSP received an award in the amount of \$1,059,407 for the period of September 30, 2010 through September 29, 2011 to implement ECHPP Phase I. On December 14, 2010, your Board approved acceptance of ECHPP Phase I funding (referenced as Enhanced HIV Prevention Planning (E-HIVPP), and delegated authority to accept future awards/amendments that were consistent with the original award through September 29, 2014.

In April 2011, the CDC released Funding Opportunity Announcement Number PS 11-1117 for ECHPP Phase II. On May 23, 2011, the DPH/DHSP submitted its application for ECHPP Phase II.

On September 24, 2011, the DPH/DHSP received an award in the amount of \$2,566,656 for the period of September 30, 2011 through September 29, 2012 for the implementation of ECHPP Phase II. On November 16, 2011, your Board was notified of DPH's use of delegated authority to accept the ECHPP Phase II award. The CDC has mandated that all jurisdictions receiving ECHPP funding implement all 14 of the required interventions listed in the program guidance, including the provision of nPEP services to populations at risk. Some examples of the required interventions include: routine testing in clinical and non-clinical settings, condom distribution to prioritized targeted HIV-positive persons, STD screening, partner services, linkage to medical care, and interventions promoting adherence to antiretroviral medications.

As required under Board Policy 5.120: Authority To Approve Increases To Board Approved Contract Amounts, on December 6, 2011, your Board was notified of DPH's request to increase or decrease funding up to 25 percent above or below the annual base maximum obligation.

County Counsel has approved Exhibit I as to form. Attachment A is the signed Sole Source Checklist.

CONTRACTING PROCESS

LAGLC is recommended for this sole source agreement because it is one of two LAC sites to participate successfully in a clinical study testing the feasibility of delivering the complex intervention safely and effectively in a community clinic setting to populations at highest risk for HIV acquisition in LAC. Since DPH plans to continue nPEP services with the OASIS Clinic through a DSO, the LAGLC is being recommended to provide services through a sole source agreement because it possesses the entire complement of wrap-around services and staffing needed to ensure that all of the components of the program are successfully implemented. LAGLC also has access to the highest risk populations in LAC for HIV acquisitions, and demonstrated successful engagement and treatment during the clinical study.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommended actions will allow DPH to execute an agreement with LAGLC for the provision of nPEP services to interrupt the transmission of HIV for up to 300 patients per year who

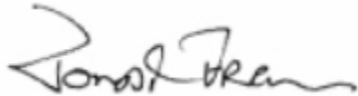
The Honorable Board of Supervisors

1/10/2012

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have had a non-occupational exposure to HIV within the previous 72 hours.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Jonathan E. Fielding". The signature is fluid and cursive, with a large initial "J" and "F".

JONATHAN E. FIELDING, M.D., M.P.H.

Director and Health Officer

JEF:nmp:ar

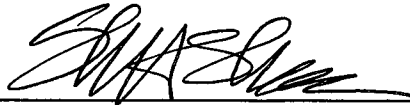
Enclosures

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors

SOLE SOURCE CHECKLIST
LOS ANGELES GAY AND LESBIAN COMMUNITY
SERVICES CENTER

Check (✓)	JUSTIFICATION FOR SOLE SOURCE PROCUREMENT OF SERVICES
	<i>Identify applicable justification and provide documentation for each checked item.</i>
	➤ Only one bona fide source for the service exists; performance and price competition are not available.
	➤ Quick action is required (emergency situation)
	➤ Proposals have been solicited but no satisfactory proposals were received.
	➤ Additional services are needed to complete an ongoing task and it would be prohibitively costly in time and money to seek a new service provider.
	➤ Maintenance service agreements exist on equipment which must be serviced by the authorized manufacturer's service representatives.
	➤ It is most cost-effective to obtain services by exercising an option under an existing contract.
	➤ It is the best interest of the County (e.g., administrative cost savings, too long a learning curve for a new service provider, etc.).
✓	<p>➤ Other reason. Please explain:</p> <p>A clinical study was conducted to determine the feasibility of delivering nPEP services in a community-based clinical setting to a diverse population at increased risk for HIV exposure, predominantly men who have sex with men. Only two agencies in Los Angeles County met the criteria to participate in the clinical study--the Los Angeles Gay and Lesbian Center (LAGLC) and the Department of Health Services' OASIS Clinic (OASIS). At the conclusion of the clinical study, both agencies demonstrated that they could deliver this complex intervention safely and effectively. To continue these services, DPH recommends a sole source with LAGLC, and plans to establish a Departmental Service Order with Oasis.</p>

In addition to their successful participation in the clinical study, LAGLC's clinic sites (the Sexual Health Care Clinic and the Jeffrey Goodman HIV Care Clinic) are well-situated to provide these services as they see high Sexually Transmitted Diseases and HIV morbidity rates and serve some of the highest-risk populations in LAC (e.g., geographic area with the highest prevalence of HIV). LAGLC also has a long history of providing culturally sensitive prevention and clinical care to racial, ethnic and sexual minorities who are at extreme risk for acquiring HIV.



Sheila Shima
Deputy Chief Executive Officer, CEO

12/27/11

Date

**HUMAN IMMUNODEFICIENCY VIRUS (HIV)/
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
NON-OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE
PROPHYLAXIS SERVICES AGREEMENT**

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Contract No. PH-Pending

**HUMAN IMMUNODEFICIENCY VIRUS (HIV)/
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
NON-OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE
PROPHYLAXIS SERVICES AGREEMENT**

THIS AGREEMENT is made and entered into this _____ day
of _____, 2011.

by and between

COUNTY OF LOS ANGELES (hereafter
"County"),

and

LOS ANGELES GAY AND LESBIAN
COMMUNITY SERVICES CENTER
(hereafter "Contractor").

WHEREAS, California Health and Safety Code Section 101025 places upon
County's Board of Supervisors the duty to preserve and protect the public's health; and

WHEREAS, California Health and Safety Code Section 101000 requires County's
Board of Supervisors to appoint a County Health Officer, who is also the Director of
County's Department of Public Health, to prevent the spread or occurrence of
contagious, infectious, or communicable diseases within the jurisdiction of County; and

WHEREAS, County has established Division of HIV and STD Programs
(hereafter "DHSP") formerly known as Office of AIDS Programs and Policy (OAPP)
under the administrative direction of County's Department of Public Health (hereafter
"DPH"); and

WHEREAS, County's DHSP is responsible for County's AIDS programs and
services; and

WHEREAS, the term "Director" as used herein refers to County's Director of DPH
or his/her authorized designee(s); and

WHEREAS, County is authorized by Government Code Section 26227 and otherwise to contract for services hereunder; and

WHEREAS, County is authorized by Government Code Section 53703 to do all acts necessary to participate in any Federal program whereby Federal funds are granted to County for purposes of health, education, welfare, public safety, and law enforcement which have not been preempted by State law; and

WHEREAS, County has been awarded grant funds from the Center of Disease Control and Prevention, Enhanced Comprehensive HIV Prevention Planning (hereafter "CDC-ECHPP"), Catalog of Federal Domestic Assistance Number (CFDA) 93.523; and

WHEREAS, Contractor agrees to abide by the requirements of the funding source and all regulations issued pursuant thereto; and

WHEREAS, Contractor possesses the competence, expertise, facilities, and personnel to provide the services contemplated hereunder; and

WHEREAS, it is the intent of the parties hereto to enter into Agreement to provide Non-Occupational Human Immunodeficiency Virus Post-Exposure Prophylaxis services (hereafter "nPEP") for compensation, as set forth herein; and

WHEREAS, this Agreement is therefore authorized under Section 44.7 of the Los Angeles County Charter and Los Angeles County Codes Section 2.121.250; and

NOW, THEREFORE, the parties hereto agree as follows:

1. TERM: The term of this Agreement shall commence Date of Board Approval and continue in full force and effect through February 28, 2013.

In any event, this Agreement may be canceled or terminated at any time by either party, with or without cause, upon the giving of at least thirty (30) calendar days

advance written notice to the other party. Further, County may also suspend the performance of services hereunder, in whole or in part, and with or without cause, upon the giving of at least a thirty (30) calendar days advance written notice to Contractor. County's notice shall set forth the extent of the suspension and the requirements for full restoration of the performance obligations.

Notwithstanding any other provision of this Agreement, the failure of Contractor or its officers, employees, agents, or subcontractors, to comply with any of the terms of this Agreement or any written directions by or on behalf of County issued pursuant hereto shall constitute a material breach hereto, and this Agreement may be terminated by County immediately. County's failure to exercise this right of termination shall not constitute a waiver of such right, which may be exercised at any subsequent time.

2. DESCRIPTION OF SERVICES:

A. Contractor shall provide the services described in Exhibit(s) and Schedules(s), and all attachments to those exhibits, attached hereto and incorporated herein by reference.

B. Contractor acknowledges that the quality of service(s) provided under this Agreement shall be at least equivalent to that which Contractor provides to all other clients it serves.

3. MAXIMUM OBLIGATION OF COUNTY:

A. During the period of date of Board approval through February 29, 2012, the maximum obligation of County for all services provided hereunder shall not exceed One Hundred Forty-Five Thousand, Four Hundred Twenty Seven Dollars (\$145,427).

Such maximum obligation is comprised entirely of CDC-ECHPP funds. This sum represents the total maximum obligation of County as shown in Schedule 1, attached hereto and incorporated herein by reference.

B. During the period of March 1, 2012 through February 28, 2013, the maximum obligation of County for all services provided hereunder shall not exceed Four Hundred Twelve Thousand, Eight Hundred Ninety-One Dollars (\$412,891).

Such maximum obligation is comprised entirely of CDC-ECHPP funds. This sum represents the total maximum obligation of County as shown in Schedule 2, attached hereto and incorporated herein by reference.

4. NONEXCLUSIVITY: Nothing herein is intended nor shall be construed as creating any exclusive arrangement with Contractor. This Agreement shall not restrict Department from acquiring similar, equal or like goods and/or services from other entities or sources.

5. COMPENSATION: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 1 and 2, and the BILLING AND PAYMENT Paragraph of the Agreement. Invoices and cost reports must be submitted and will be reimbursed in accordance with approved line-item detailed budgets.

6. BILLING AND PAYMENT: Where applicable, County shall compensate Contractor services hereunder on a fee for service, cost reimbursement and/or modified cost reimbursement at the set fee-for-service rate(s), actual reimbursable net costs

and/or any combination thereof incurred by Contractor in performing services hereunder.

A. Monthly Billing: Contractor shall bill County monthly in arrears. All billings shall include a financial invoice and all required programmatic reports and/or data. All billing shall clearly reflect all required information as specified on forms provided by County regarding the services for which claims are to be made and any and all payments made to Contractor by, or on behalf of, clients/patients. Billings shall be submitted to County within thirty (30) calendar days after the close of each calendar month. Within a reasonable period of time following receipt of a complete and correct monthly billing, County shall make payment in accordance with the benefit specialty services actual reimbursable net cost schedule attached hereto.

(1) Payment for all services provided hereunder shall not exceed the aggregate maximum monthly payment set out in the schedule for the corresponding exhibit attached hereto.

(2) No single payment to Contractor for services provided hereunder shall exceed the maximum monthly payment set out in the schedule(s) for the corresponding exhibit, unless prior approval from Director to exceed the maximum monthly payment has been granted pursuant to the BILLING AND PAYMENT Paragraph of this Agreement. To the extent that there have been lesser payments for services under this Agreement, the resultant savings may be used to pay for prior or future

monthly billings for services in excess of the maximum monthly payment in County's sole discretion.

(3) While payments shall be made in accordance with the fee-for-service rate(s) set out in the schedule(s) hereto, Contractor, if requested by County, State, or federal representatives must be able to produce proof of actual costs incurred in the provision of units of services hereunder.

(4) If the actual costs are less than the fee-for-service rate(s) set out in the schedule(s), Contractor shall be reimbursed for actual costs.

B. Audit Settlements:

(1) If an audit conducted by federal, State, and/or County representatives finds that units of service, actual reimbursable net costs for any services and/or combination thereof furnished hereunder are lower than units of service and/or reimbursement for stated actual net costs for any services for which payments were made to Contractor by County, then payment for the unsubstantiated units of service and/or unsubstantiated reimbursement of stated actual net costs for any services shall be repaid by Contractor to County. For the purpose of this BILLING AND PAYMENT Paragraph, an "unsubstantiated unit of service" shall mean a unit of service for which Contractor is unable to adduce proof of performance of that unit of service and "unsubstantiated reimbursement of stated actual net costs" shall mean a stated actual net costs for which Contractor is unable to adduce proof of performance and/or receipt of the actual net cost for any service.

(2) If an audit conducted by federal, State, and/or County representatives finds that actual costs for a unit service provided hereunder are less than the County's payment than those units of service, then Contractor shall repay County the difference immediately upon request or County has the right to withhold and/or offset that repayment obligation against future payments.

(3) If within forty-five (45) calendar days of termination of the contract period, such audit finds that the units of service, allowable costs of services and/or any combination thereof furnished hereunder are higher than the units of service, allowable costs of services and/or payments made by County, then the difference may be paid to Contractor, not to exceed the County Maximum Obligation.

C. The parties acknowledge that County is the payor of last resort for services provided hereunder. Accordingly, in no event shall County be required to reimburse Contractor for those costs of services provided hereunder which are covered by revenue from or on behalf of clients/patients or which are covered by funding from other governmental contracts, agreements or grants.

D. In no event shall County be required to pay Contractor for units of services and/ or reimburse Contractor for those costs of services provided hereunder which are covered by revenue from or on behalf of clients/patients or which are covered by funding from other governmental contracts, agreements or grants.

E. In no event shall County be required to pay Contractor for units of services that are not supported by actual costs.

F. In the event that Contractor's actual cost for a unit of service are less than fee-for-service rate(s) set out in the schedule(s), the Contractor shall be reimbursed for its actual costs only.

G. In no event shall County be required to pay Contractor more for all services provided hereunder than the maximum obligation of County as set forth in the MAXIMUM OBLIGATION OF COUNTY Paragraph of this Agreement, unless otherwise revised or amended under the terms of this Agreement.

H. Travel shall be budgeted and expensed according to applicable federal, State, and/or local guidelines. Prior authorization, in writing, shall be required for travel outside Los Angeles County unless such expense is explicitly approved in the contract budget. Request for authorization shall be made in writing to Director and shall include the travel dates, locations, purpose/agenda, participants, and costs.

I. Withholding Payment:

(1) Subject to the reporting and data requirements of this Agreement and the exhibit(s) attached hereto, County may withhold any claim for payment by Contractor if any report or data is not delivered by Contractor to County within the time limits of submission as set forth in this Agreement, or if such report, or data is incomplete in accordance with requirements set forth in this Agreement. This withholding may be

invoked for the current month and any succeeding month or months for reports or data not delivered in a complete and correct form.

(2) Subject to the provisions of the TERM and ADMINISTRATION Paragraphs of this Agreement, and the exhibits(s) attached hereto, County may withhold any claim for payment by Contractor if Contractor has been given at least thirty (30) calendar days' notice of deficiency(ies) in compliance with the terms of this Agreement and has failed to correct such deficiency(ies). This withholding may be invoked for any month or months for deficiency(ies) not corrected.

(3) Upon acceptance by County of all report(s) and data previously not accepted under this provision and/or upon correction of the deficiency(ies) noted above, County shall reimburse all withheld payments on the next regular monthly claim for payment by Contractor.

(4) Subject to the provisions of the exhibit(s) of this Agreement, if the services are not completed by Contractor within the specified time, County may withhold all payments to Contractor under this Agreement between County and Contractor until proof of such service(s) is/are delivered to County.

(5) In addition to Subparagraphs (1) through (4) immediately above, Director may withhold claims for payment by Contractor which are delinquent amounts due to County as determined by a cost report settlement, audit report settlement, or financial evaluation report, resulting from this or prior years' Agreement(s).

J. Contractor agrees to reimburse County for any federal, State, or County audit exceptions resulting from noncompliance herein on the part of Contractor or any subcontractor.

K. Fiscal Viability: Contractor must be able to carry the costs of its program without reimbursement from the contract for at least ninety (90) days at any point during the term of the contract in this Agreement.

L. Contractor Expenditure Reduction Flexibility: In order for County to maintain flexibility with regards to budget and expenditures reductions, Contractor agrees that Director may cancel this Agreement, with or without cause, upon the giving of ten (10) calendar days written notice to Contractor; or notwithstanding, ALTERATION OF TERMS of this Agreement, Director, may, consistent with federal, State, and/or County budget reductions, renegotiate the scope/description of work, maximum obligation, and budget of this Agreement via an Administrative Amendment, as mutually agreed to and executed by the parties therein.

M. Fiscal Disclosure: Contractor shall prepare and submit to Director, within ten (10) calendar days following execution of this Agreement, a statement executed by Contractor's duly constituted officers, containing the following information:

(1) A detailed statement listing all sources of funding to Contractor including private contributions. The statement shall include the nature of the funding, services to be provided, total dollar amount, and period of time of such funding.

(2) If during the term of this Agreement, the source(s) of Contractor's funding changes, Contractor shall promptly notify the Director in writing detailing such changes.

N. Clients/Patients: In the event of termination or suspension of this Agreement, Contractor shall:

(1) If clients/patients are treated hereunder, make immediate and appropriate plans to transfer or refer all clients/patients treated under this Agreement to other agencies for continuing care in accordance with the client's/patient's needs. Such plans shall be approved by Director before any transfer or referral is completed, except in such instance, as determined by Contractor, where an immediate client/patient transfer or referral is indicated. In such instances, Contractor may make an immediate transfer or referral.

(2) Immediately eliminate all new costs and expenses under this Agreement. New costs and expenses include, but are not limited to, those associated with new client/patient admissions. In addition, Contractor shall immediately minimize all other costs and expenses under this Agreement. Contractor shall be reimbursed only for reasonable and necessary costs or expenses incurred after receipt of notice of termination.

(3) Promptly report to County in writing all information necessary for the reimbursement of any outstanding claims and continuing costs.

O. Provide County's DHSP within thirty (30) calendar days after such termination date, an annual cost report as set forth in the ANNUAL COST REPORT Paragraph, hereunder.

P. Real Property Disclosure: If Contractor is renting, leasing, or subleasing, or is planning to rent, lease, or sublease, any real property where persons are to receive services hereunder, Contractor shall prepare and submit to DHSP, within ten (10) calendar days following execution of this Agreement, an affidavit sworn to and executed by Contractor's duly constituted officers, containing the following information:

(1) The location by street address and city of any such real property.

(2) The fair market value of any such real property as such value is reflected on the most recently issued County Tax Collector's tax bill.

(3) A detailed description of all existing and pending rental agreements, leases, and subleases with respect to any such real property, such description to include: the term (duration) of such rental agreement, lease, or sublease; the amount of monetary consideration to be paid to the lessor or sublessor over the term of the rental agreement, lease or sublease; the type and dollar value of any other consideration to be paid to the lessor or sublessor over the term of the rental agreement, lease or sublease; the full names and addresses of all parties who stand in the position of lessor or sublessor; if the lessor or sublessor is a private corporation and its shares are not publicly traded (on a stock exchange or

over-the-counter), a listing by full names of all officers, directors, and stockholders thereof; and if the lessor or sublessor is a partnership, a listing by full names of all general and limited partners thereof.

(4) A listing by full names of all Contractor's officers, directors, members of its advisory boards, members of its staff and consultants, who have any family relationships by marriage or blood with a lessor or sublessor referred to in Subparagraph (3) immediately above, or who have any financial interest in such lessor's or sublessor's business, or both. If such lessor or sublessor is a corporation or partnership, such listing shall also include the full names of all Contractor's officers, members of its advisory boards, members of its staff and consultants, who have any family relationship, by marriage or blood, to an officer, director, or stockholder of the corporation, or to any partner of the partnership. In preparing the latter listing, Contractor shall also indicate the name(s) of the officer(s), director(s), stockholder(s), or partner(s), as appropriate, and the family relationship which exists between such person(s) and Contractor's representatives listed.

(5) If a facility of Contractor is rented or leased from a parent organization or individual who is a common owner (as defined by Federal Health Insurance Manual 15, Chapter 10, Paragraph 1002.2), Contractor shall only charge the program for costs of ownership. Costs of ownership shall include depreciation, interest, and applicable taxes.

True and correct copies of all written rental agreements, leases, and subleases with respect to any such real property shall be appended to such affidavit and made a part thereof.

7. FUNDING/SERVICES ADJUSTMENTS AND REALLOCATIONS:

A. Upon Director's specific written approval, County may increase or decrease the funding or reallocate funds to an Exhibit, Schedule and/or Budget category in this Agreement where such funds can be more effectively used by Contractor, up to twenty-five percent (25%) above or below each term's annual base maximum obligation and make corresponding service adjustments, as necessary, based on the following: (1) if additional monies are available from federal, State, or County funding sources; (2) if a reduction of monies occur from federal, State, or County funding sources; and/or (3) if County determines from reviewing Contractor's records of service delivery and billings to County that a significant underutilization of funds provided under this Agreement will occur over its term.

All funding adjustments and reallocation as allowed under this Paragraph will not be retroactive, but will apply to future services following the provision of written notice from Director, or his/her designee, to Contractor. Reallocation of funds in excess of the aforementioned amount shall be approved by County's Board of Supervisors. Any change to the County maximum obligation or reallocation of funds to an Exhibit, Schedule, and/or Budget category in this Agreement shall be effectuated by an amendment to this Agreement pursuant to the ALTERATION OF TERMS Paragraph of this Agreement.

B. County and Contractor shall review Contractor's expenditures and commitments to utilize any funds, which are specified in this Agreement for the services hereunder and which are subject to time limitations as determined by Director, midway through each County fiscal year during the term of this Agreement, midway through the applicable time limitation period for such funds if such period is less than a County fiscal year, and/or at any other time or times during each County fiscal year as determined by Director. At least fifteen (15) calendar days prior to each such review, Contractor shall provide Director with a current update of all of Contractor's expenditures and commitments of such funds during such fiscal year or other applicable time period.

8. BUDGET REDUCTIONS: In the event that the County's Board adopts, in any fiscal year, a County Budget which provides for reductions in the salaries and benefits paid to the majority of County employees and imposes similar reductions with respect to County Contracts, the County reserves the right to reduce its payment obligation under this Contract correspondingly for that fiscal year and any subsequent fiscal year during the term of this Contract (including any extensions), and the services to be provided by the Contractor under this Contract shall also be reduced correspondingly. The County's notice to the Contractor regarding said reduction in payment obligation shall be provided within thirty (30) calendar days of the Board's approval of such actions. Except as set forth in the preceding sentence, the Contractor shall continue to provide all of the services set forth in this Contract.

9. COUNTY'S OBLIGATION FOR FUTURE FISCAL YEARS: Notwithstanding any other provisions of this Agreement, County shall not be obligated by any activity or

services performed hereunder, or by any provisions of this Agreement, during any of County's fiscal years (July 1 – June 30) unless and until the Board appropriates funds for this Agreement in County's budget for each such fiscal year. In the event that funds are not appropriated for this Agreement, then this Agreement shall be deemed to have terminated on June 30th of the last County fiscal year for which funds were appropriated. County shall notify Contractor in writing of such non-appropriation of funds at the earliest possible date. If for any reason funding to this Agreement is terminated or reduced, County shall have the right to immediately terminate this Agreement in whole or in part. Notice of such termination shall be served upon Contractor in writing.

10. NO PAYMENT FOR SERVICES PROVIDED FOLLOWING EXPIRATION / TERMINATION OF AGREEMENT: Contractor acknowledges that no services shall be provided beyond the expiration date of this Agreement even if such services were requested by County. Contractor shall have no claim against County for payment of any money or reimbursement, of any kind whatsoever, for any service provided by Contractor after the expiration or other termination of this Agreement. Should Contractor receive any such payment it shall immediately notify County and shall immediately repay all such funds to County. Payment by County for services rendered after expiration/termination of this Agreement shall not constitute a waiver of County's right to recover such payment from Contractor. This provision shall survive the expiration or other termination of this Agreement.

11. INDEMNIFICATION: Contractor shall indemnify, defend, and hold harmless County and its Special Districts, elected and appointed officers, employees, and agents from and against any and all liability, including but not limited to demands, claims,

actions, fees, costs, and expenses (including attorney and expert witness fees), arising from or connected with Contractor's acts and/or omissions arising from and/or relating to this Agreement.

12. GENERAL PROVISIONS FOR ALL INSURANCE COVERAGES: Without limiting Contractor's indemnification of County and in the performance of this Agreement and until all of its obligations pursuant to this Agreement have been met, Contractor shall provide and maintain at its own expense insurance coverage satisfying the requirements specified in Paragraphs 12 and 13 of this Agreement. These minimum insurance coverage terms, types and limits (the "Required Insurance") also are in addition to and separate from any other contractual obligation imposed upon Contractor pursuant to this Agreement. The County in no way warrants that the Required Insurance is sufficient to protect the Contractor for liabilities which may arise from or relate to this Agreement.

A. Evidence of Coverage and Notice to County: A certificate(s) of insurance coverage (Certificate) satisfactory to County, and a copy of an Additional Insured endorsement confirming County and its Agents (defined below) has been given Insured status under the Contractor's General Liability policy, shall be delivered to the County at the address shown below and provided prior to commencing services under this Contract.

Renewal Certificates shall be provided to County not less than ten (10) days prior to Contractor's policy expiration dates. The County reserves the right to obtain complete, certified copies of any required Contractor and/or Sub-Contractor insurance policies at any time.

Certificates shall identify all Required Insurance coverage types and limits specified herein, reference this Contract by name or number, and be signed by an authorized representative of the insurer(s). The Insured party named on the Certificate shall match the name of the Contractor identified as the contracting party in this Contract. Certificates shall provide the full name of each insurer providing coverage, its NAIC (National Association of Insurance Commissioners) identification number, its financial rating, the amounts of any policy deductibles or self-insured retentions exceeding fifty thousand (\$50,000) dollars, and list any County required endorsement forms.

Neither the County's failure to obtain, nor the County's receipt of, or failure to object to a non-complying insurance certificate or endorsement, or any other insurance documentation or information provided by the Contractor, its insurance broker(s) and/or insurer(s), shall be construed as a waiver of any of the Required Insurance provisions.

Certificates and copies of any required endorsements shall be delivered to:

County of Los Angeles, Department of Public Health
Contract Monitoring Division
5555 Ferguson Drive, Suite 210
City of Commerce, California 90022

Attention: Division Chief

County of Los Angeles, Department of Public Health
Division of HIV and STD Programs
600 South Commonwealth Avenue, 10th Floor
Los Angeles, California 90005

Attention: Contract Administration Division, Chief

Contractor also shall promptly report to County any injury or property damage accident or incident, including any injury to a Contractor employee occurring on county property, and any loss, disappearance, destruction, misuse, or theft of County property, monies or securities entrusted to Contractor.

Contractor also shall promptly notify County of any third party claim or suit files against Contractor or any of its subcontractors which arises from or relates to this Agreement, and could result in the filing of a claim or lawsuit against Contractor and/or County.

B. Additional Insured Status and Scope of Coverage: The County of Los Angeles, its Special Districts, Elected Officials, Officers, Agents, Employees and Volunteers (collectively County and its Agents) shall be provided additional insured status under Contractor's General Liability policy with respect to liability arising out of Contractor's ongoing and completed operations performed on behalf of the County. County and its Agents additional insured status shall apply with respect to liability and defense of suits arising out of the Contractor's acts or omissions, whether such liability is attributable to the Contractor or to the County. The full policy limits and scope of protection also shall apply to the County and its Agents as an additional insured, even if they exceed the County's minimum Required Insurance specifications herein. Use of an automatic additional insured endorsement form is acceptable providing it satisfies the Required Insurance provisions herein.

C. Cancellation of or Changes in Insurance: Contractor shall provide County with, or Contractor's insurance policies shall contain a provision that

County shall receive, written notice of cancellation or any change in Required Insurance, including insurer, limits of coverage, term of coverage or policy period. The written notice shall be provided to County at least ten (10) days in advance of cancellation for non-payment of premium and thirty (30) days in advance for any other cancellation or policy change. Failure to provide written notice of cancellation or any change in Required Insurance may constitute a material breach of the Agreement, in the sole discretion of the County, upon which the County may suspend or terminate this Agreement.

D. Failure to Maintain Insurance: Contractor's failure to maintain or to provide acceptable evidence that it maintains the Required Insurance shall constitute a material breach of the Agreement, upon which County immediately may withhold payments due to Contractor, and/or suspend or terminate this Contract. County, at its sole discretion, may obtain damages from Contractor resulting from said breach. Alternatively, the County may purchase the Required Insurance, and without further notice to Contractor, deduct the premium cost from sums due to Contractor or pursue Contractor reimbursement.

E. Insurer Financial Ratings: Insurance coverage shall be placed with insurers acceptable to the County with an A.M. Best rating of not less than A: VII unless otherwise approved by County.

F. Contractor's Insurance Shall Be Primary: Contractor's insurance policies, with respect to any claims relates to this Agreement, shall be primary with respect to all other sources of coverage available to Contractor. Any

County maintained insurance or self-insurance coverage shall be in excess of and not contribute to any Contractor coverage.

G. Waivers of Subrogation: To the fullest extent permitted by law, the Contractor hereby waives its rights and its insurer(s)' rights of recovery against County under all the Required Insurance for any loss arising from or relating to this Agreement. The Contractor shall require its insurers to execute any waiver of subrogation endorsements which may be necessary to affect such waiver.

H. Compensation for County Costs: In the event that Contractor fails to comply with any of the indemnification or insurance requirements of this Agreement, and such failure to comply results in any costs to County, Contractor shall pay full compensation for all costs incurred by County.

I. Subcontractors Insurance Coverage Requirements: Contractor shall include all subcontractors as insured under Contractor's own policies, or shall provide County with each subcontractor's separate evidence of insurance coverage. Contractor shall be responsible for verifying each subcontractor complies with the Required Insurance provisions herein, and shall require that each subcontractor name the County and Contractor as additional insured on the subcontractor's General Liability policy. Contractor shall obtain County's prior review and approval of any subcontractor request for modification of the Required Insurance.

J. Deductibles and Self-Insured Retentions (SIRs): Contractor's policies shall not obligate the County to pay any portion of any Contractor deductible or SIR. The County retains the right to require Contractor to reduce or eliminate

policy deductibles and SIRs as respects the County, or to provide a bond guaranteeing Contractor's payment of all deductibles and SIRs, including all related claims investigation, administration, and defense expenses. Such bond shall be executed by a corporate surety licensed to transact business in the State of California.

K. Claims Made Coverage: If any part of the Required Insurance is written on a claim made basis, any policy retroactive date shall precede the effective date of this Agreement. Contractor understands and agrees it shall maintain such coverage for a period of not less than three (3) years following Contract expiration, termination, or cancellation.

L. Application of Excess Liability Coverage: Contractors may use a combination of primary, and excess insurance policies which provide coverage as broad as ("follow form" over) the underlying primary policies, to satisfy the Required Insurance provisions.

M. Separation of Insureds: All liability policies shall provide cross-liability coverage as would be afforded by the standard ISO (Insurance Services Office, Inc.) separation of insureds provision with no insured versus insured exclusions or limitations.

N. Alternative Risk Financing Programs: The County reserves the right to review, and then approve, Contractor use of self-insurance, risk retention groups, risk purchasing groups, pooling arrangements and captive insurance to satisfy the Required Insurance provisions. The County and its Agents shall be designated as an Additional Covered Party under any approved program.

O. County Review and Approval of Insurance Requirements: The County reserves the right to review and adjust the Required Insurance provisions, conditioned upon County's determination of changes in risk exposures. The County and its Agents shall be designated as an Additional Covered Party under any approved program.

13. INSURANCE COVERAGE REQUIREMENTS:

A. Commercial General Liability: Insurance (providing scope of coverage equivalent to ISO policy form CG 00 01), naming County and its Agents as an additional insured, with limits of not less than the following:

General Aggregate:	\$2 Million
Products/Completed operations Aggregate:	\$1 Million
Personal and Advertising Injury:	\$1 Million
Each Occurrence:	\$1 Million

Such coverage also shall cover liability arising from any actual or alleged infringement of any patent or copyright, or other property rights of any third party. The policy also shall be endorsed to provide media liability coverage for claims arising out of Contractor's placement of print and audiovisual media. Alternatively, Contractor may provide such media liability coverage under a separate policy or through Contractor's errors and omissions policy.

B. Automobile Liability: Insurance (providing scope of coverage equivalent to ISO policy form CA 00 01) with limits of not less than \$1 Million for bodily injury and property damage, in combined or equivalent split limits, for each single accident. Insurance shall cover liability arising out of Contractor's

use of autos pursuant to this Agreement, including owned, leased, hired, and/or non-owned autos, or coverage for “any auto”, as each may be applicable.

C. Workers Compensation and Employers’ Liability: insurance or qualified self-insurance satisfying statutory requirements, which includes Employers’ Liability coverage with limits of not less than \$1 Million per accident. If Contractor will provide leased employees, or, is an employee leasing or temporary staffing firm or a professional employer organization (PEO), coverage also shall include an Alternate Employer Endorsement (providing scope of coverage equivalent to ISO policy form WC 00 03 01 A) naming the County as the Alternate Employer, and the endorsement form shall be modified to provide that County will receive not less than thirty (30) days advance written notice of cancellation of this coverage provision. If applicable to Contractor’s operations, coverage shall be arranged to satisfy the requirements of any federal workers or workmen’s compensation law or any federal occupational disease law. In all cases, the above insurance also shall include Employers’ Liability coverage with limits of not less than the following:

Each Accident:	\$1 Million
Disease – Policy Limit:	\$1 Million
Disease – Each Employee:	\$1 Million

D. Professional Liability /Errors and Omissions: Insurance covering Contractor’s liability arising from or related to this Agreement, any error, omission, negligent or wrongful act of Contractor, its officer or employees with limits of not less than \$1 Million per claim and \$3 Million aggregate. Further,

Contractor understands and agrees it shall maintain such coverage for a period of not less than three (3) years following this Agreement's expiration, termination, or cancellation.

E. Sexual Misconduct Liability: Insurance covering actual or alleged claims for sexual misconduct and/or molestation with limits of not less than \$2 Million per claim and \$2 Million aggregate, and claims for negligent employment, investigation, supervision, training or retention of, or failure to report to proper authorities, a person(s) who committed any act of abuse, molestation, harassment, mistreatment or maltreatment of a sexual nature.

14. ASSIGNMENT AND DELEGATION:

A. Contractor shall not assign its rights or delegate its duties under this Agreement, or both, whether in whole or in part, without the prior written consent of County, in its discretion, and any attempted assignment or delegation without such consent shall be null and void. For purposes of this Subparagraph, County consent shall require a written amendment to the Agreement, which is formally approved and executed by the parties. Any payments by County to any approved delegate or assignee on any claim under this Agreement shall be deductible, at County's sole discretion, against the claims, which Contractor may have against County.

B. Shareholders, partners, members, or other equity holders of Contractor may transfer, sell, exchange, assign, or divest themselves of any interest they may have therein. However, in the event any such transfer, exchange, assignment, or divestment is effected in such a way as to give

majority control of Contractor to any person(s), corporation, partnership, or legal entity other than the majority controlling interest therein at the time of execution of the Agreement, such disposition is an assignment requiring the prior written consent of County in accordance with applicable provisions of this Agreement.

C. Any assumption, assignment, delegation, or takeover of any of the Contractor's duties, responsibilities, obligations, or performance of same by any entity other than Contractor, whether through assignment, subcontract, delegation, merger, buyout, or any other mechanism, with or without consideration for any reason whatsoever without County's express prior written approval, shall be a material breach of the Agreement which may result in the termination of this Agreement. In the event of such termination, County shall be entitled to pursue the same remedies against Contractor as it could pursue in the event of default by Contractor.

15. SUBCONTRACTING:

A. For purposes of this Agreement, all subcontracts must first be approved in writing by Director. Contractor's written request to Director for approval to enter into a subcontract shall be made at least thirty (30) calendar days prior to the subcontractor's proposed effective date, and shall include:

(1) Identification of the proposed subcontractor, who shall be licensed as appropriate for provision of subcontract services, and an explanation of why and how the proposed subcontractor was selected, including the degree of competition involved.

(2) A detailed description of the services to be provided by the subcontractor.

(3) The proposed subcontract amount and manner of compensation, if any, together with Contractor's cost or price analysis thereof.

(4) A copy of the proposed subcontract. Any later modification of such subcontract shall take the form of a formally written subcontract amendment which also must be approved in writing by Director in the same manner as described above, before such amendment is effective.

(5) Any other information and/or certification(s) requested by Director.

B. Director shall review Contractor's request to subcontract and shall determine, in his/her sole discretion, whether or not to consent to such a request on a case-by-case basis.

C. Subcontracts shall be made in the name of Contractor and shall not bind nor purport to bind County. The making of subcontracts hereunder shall not relieve Contractor of any requirements under this Agreement, including, but not limited to, the duty to properly supervise and coordinate the work of subcontractors. Further, Director's approval of any subcontract shall also not be construed to limit in any way, any of County's rights or remedies contained in this Agreement.

D. In the event that Director consents to any subcontracting, Contractor shall be solely liable and responsible for any and all payments or other compensation to all subcontractors, and their officers, employees, and agents.

E. In the event that Director consents to any subcontracting, such consent shall be subject to County's right to terminate, in whole or in part, any subcontract at any time upon written notice to Contractor when such action is deemed by County to be in its best interest. County shall not be liable or responsible in any way to Contractor, or any subcontractor, or to any officers, employees, or agents, of Contractor, or any subcontractor, for any liability, damages, costs, or expenses, arising from or related to County's exercising of such a right.

F. Subcontracts shall contain the following provision: "This contract is a subcontract under the terms of a prime contract with the County of Los Angeles and shall be subject to all of the provisions of such prime contract." Further, Contractor shall also reflect as subcontractor requirements in the subcontract form all of the requirements of the INDEMNIFICATION, GENERAL PROVISIONS FOR ALL INSURANCE COVERAGES, INSURANCE COVERAGE REQUIREMENTS, COMPLIANCE WITH APPLICABLE LAW, CONFLICT OF TERMS, and ALTERATION OF TERMS paragraphs of the body of this Agreement, and all of the provisions of the Additional Provisions attachment.

Contractor shall deliver to Director a fully executed copy of each subcontract entered into by Contractor, as it pertains to the provision of services under this Agreement, on or immediately after the effective date of the

subcontract, but in no event, later than the date any services are to be performed under the subcontract.

G. Director is hereby authorized to act for and on the behalf of County pursuant to this Paragraph, including but not limited to, consenting to any subcontracting.

16. COMPLIANCE WITH APPLICABLE LAWS:

A. Contractor shall comply with the requirements of all federal, State, and local laws, ordinances, regulations, rules, guidelines, and directives, applicable to its performance hereunder. To the extent there is any conflict between federal and State or local laws, the former shall prevail.

Any reference to a specific statute, regulation, or any other document not prepared by County is deemed to include a reference to any amendment thereto as of the effective date of such amendment; further, this Agreement shall be interpreted and the parties' duties and obligations under this Agreement shall be consistent with any amendment to any applicable statute, regulation or other document not prepared by County which occurs after the effective date of the Agreement.

B. Contractor shall indemnify and hold harmless County from and against any and all loss, damage, liability, or expense resulting from any violation on the part of Contractor, its officers, employees, or agents, of such federal, State, or local laws, regulations, guidelines, or directives.

17. COMPLIANCE WITH CIVIL RIGHTS LAWS: Contractor hereby assures that it will comply with Subchapter VI of the Civil Rights Act of 1964, 42 USC Sections 2000

(e) (1) through 2000 (e) (17), to the end that no person shall, on the grounds of race, creed, color, sex, religion, ancestry, age, condition of physical handicap, marital status, political affiliation, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under this Agreement or under any project, program, or activity supported by this Agreement.

18. ADDITIONAL PROVISIONS: Attached hereto and incorporated herein by reference, is a document labeled "ADDITIONAL PROVISIONS". The terms and conditions therein contained are part of this Agreement.

19. CONSTRUCTION: To the extent there are any rights, duties, obligations, or responsibilities enumerated in the recitals or otherwise in this Agreement, they shall be deemed a part of the operative provisions of this Agreement and are fully binding upon the parties.

20. CONFLICT OF TERMS: To the extent there exists any conflict or inconsistency between the language of this Agreement (including its ADDITIONAL PROVISIONS), and that of any of any Exhibit(s), Attachment(s), Schedule(s) and any other documents incorporated herein by reference, the language found within this Agreement shall govern and prevail.

21. ALTERATION OF TERMS: The body of this Agreement (including its ADDITIONAL PROVISIONS), and any Exhibit(s) attached hereto, fully expresses all understandings of the parties concerning all matters covered and shall constitute the total Agreement. No addition to, or alteration of, the terms of this Agreement, whether by written or verbal understanding of the parties, their officers, agents or employees, shall be valid and effective unless made in the form of a written amendment to this

Agreement which is formally approved and executed by the parties in the same manner as this Agreement.

22. QUALITY MANAGEMENT: Contractor shall implement a Quality Management (QM) program that assesses the extent to which the care and services provided are consistent with federal (e.g., Public Health Services and CDC Guidelines), State, and local standards of HIV/AIDS care and services. The QM program shall at a minimum:

- A. Identify leadership and accountability of the medical director or executive director of the program;
- B. Use measurable outcomes and data collected to determine progress toward established benchmarks and goals;
- C. Focus on linkages to care and support services;
- D. Track client perception of their health and effectiveness of the service received;
- E. Serve as a continuous quality improvement (CQI) process reported to senior leadership annually.

23. QUALITY MANAGEMENT PLAN: Contractor shall develop program on a written QM plan. Contractor shall develop one (1) agency-wide QM plan that encompasses all HIV/AIDS care services. Contractor shall submit to DHSP within sixty (60) days of the receipt of this fully executed Agreement, its written QM plan. The plan shall be reviewed and updated as needed by the agency's QM committee, and signed by the medical director or executive director. The implementation of the QM plan may

be reviewed by DHSP staff during its onsite program review. The written QM plan shall at a minimum include the following seven (7) components:

A. Objectives: QM plan should delineate specific goals and objectives that reflect the program's mission, vision and values.

B. QM Committee: The plan shall describe the purpose of the Quality Management Committee, its composition, meeting frequency (quarterly, at minimum) and required documentation (e.g., minutes, agenda, sign-in sheets, etc.). Programs that already have an established advisory committee need not create a separate QM Committee, provided that the existing advisory committee's composition and activities conform to QM program objectives and committee requirements.

C. Selection of a QM Approach: The QM plan shall describe an elected QM approach, such as Plan-Do-Study-Act (PDSA) and/or other models.

D. Implementation of QM Program:

(1) Selection of Clinical and/or Performance Indicators – At a minimum, Contractor shall collect and analyze data for at least three (3) clinical and/or performance indicators, two (2) of which shall be selected from a list of DHSP approved QM indicators. Contractor may select other aspects of care or treatment as its third clinical/performance indicator or select from the DHSP approved list of QM indicators. An updated QM indicator list will be available from DHSP.

(a) Percent of patients reporting progress toward resolving the problems that caused them to seek or be referred to psychiatric treatment;

(b) Percent of patients with an improvement in GAF score over the course of their treatment;

(c) Percent of patients reporting a reduction in transmission risk behaviors;

(d) Percent of patients who keep their mental health appointments;

(e) Percent of patients who report satisfaction with mental health services they receive.

In addition, the agency can measure other aspects of care and services as needed.

(2) Data Collection Methodology – Contractor shall describe its sampling strategy (e.g., frequency, percentage of sample sized), collection method (e.g., random chart audit, interviews, surveys, etc.), and implement data collection tools for measuring clinical/performance indicators and/or other aspects of care. Sampling shall be, at a minimum, ten percent (10%) or thirty (30) charts, whichever is less.

(3) Data Analysis – Contractor shall routinely review and analyze clinical/performance indicator monitoring results at the QM committee. The findings of the data analyses shall be communicated with all program staff involved.

(4) Improvement Strategies - QM committee shall identify improvement strategies to be implemented, track progress of improvement efforts, and aim to sustain achieved improvements.

E. Client Feedback Process: The QM plan shall describe the mechanism for obtaining ongoing feedback from clients regarding the accessibility and appropriateness of service and care. Feedback shall include the degree to which the service meets client needs and satisfaction. Client input shall be discussed in the agency's QM Committee meetings on a regular basis for the enhancement of service delivery. Aggregate data shall be reported to the QM Committee annually for continuous program improvement.

F. Client Grievance Process: Contractor shall establish policies and procedures for addressing and resolving client's grievance at the level closest to the source within agency. Grievance data shall be tracked, trended, and reported to the agency's QM committee for discussion and resolution of quality of care issues identified. The information shall be made available to DHSP staff during program reviews.

G. Incident Reporting: Contractor shall comply with incident and or sentinel event reporting as required by applicable federal and State laws, statutes, and regulations. Contractor shall furnish to DHSP Executive Office, upon the occurrence, during the operation of the facility, reports of incidents and/or sentinel events specified as follows:

(1) A report shall be made to the appropriate licensing authority and to DHSP within the next business day from the date of the event,

pursuant to federal and State laws, statutes, and regulations. Reportable events reported shall include the following:

(a) Any unusual incident and sentinel event which threatens the physical or emotional health or safety of any person to include but not limited to suicide, medication error, delay in treatment, and serious injury.

(b) Any suspected physical or psychological abuse of any person, such as child, adult, and elderly.

(2) In addition, a written report containing the information specified shall be submitted to appropriate agency and DHSP immediately following the occurrence of such event. Information provided shall include the following:

(a) Client's name, age, and sex;

(b) Date and nature of event;

(c) Disposition of the case;

(d) Staffing pattern at the time of the incident.

24. QUALITY MANAGEMENT PROGRAM MONITORING: To determine compliance, DHSP shall review contractor's QM program annually. A numerical score will be issued to the contractor's QM program based on one hundred percent (100%) as the maximum score. Contractor's QM program shall be assessed for implementation of the following components:

A. Details of the QM plan (QM Objectives, QM Committee, and QM Approach Selection);

- B. Implementation of QM Program;
- C. Client Feedback Process;
- D. Client Grievance Process;
- E. Incident Reporting;

25. CONTRACTOR'S OFFICES: Contractor's primary business offices are located at: 1625 North Schrader Boulevard, Los Angeles, California 90028. Contractor's primary business telephone number is (323) 993-7609 and facsimile/FAX number (323) 308-4002. Contractor shall notify in writing County's DHSP Director, any change in its primary business address, business telephone number, and/or facsimile/FAX number used in the provision of services herein, at least ten (10) days prior to the effective date thereof.

If during the term of this Agreement, the corporate or other legal status of Contractor changes, or the name of Contractor changes, then Contractor shall notify County's DHSP Director, in writing detailing such changes at least thirty (30) days prior to the effective date thereof.

26. NOTICES: Any and all notices required, permitted, or desired to be given hereunder by one party to the other shall be in writing and shall be delivered to the other party personally or by United States mail, certified or registered, postage prepaid, return receipt requested, to the parties at the following addresses and to the attention of the person named. Director shall have the authority to issue all notices which are required or permitted by County hereunder. Addresses and persons to be notified may be changed by the parties by giving ten (10) calendar days prior written notice thereof to the parties.

To County: 1. Department of Public Health
 Division of HIV and STD Programs
 600 South Commonwealth Avenue
 10th Floor
 Los Angeles, California 90005

Attention: Director

2. Department of Public Health
 Contracts and Grants Division
 313 North Figueroa Street
 6th Floor West
 Los Angeles, California 90012

Attention: Chief

To Contractor: Los Angeles Gay and Lesbian
 Community Services Center
 1625 North Schrader Boulevard,
 Los Angeles, California 90028

Attention: Lorri L. Jean, Esq.
Chief Executive Director

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IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Agreement to be subscribed by its Director of Public Health, and Contractor has caused this Agreement to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By _____
Jonathan E. Fielding, M.D., MPH
Director and Health Officer

LOS ANGELES GAY AND LESBIAN
COMMUNITY SERVICES CENTER

Contractor

By _____
Signature

Printed Name

Title _____
(AFFIX CORPORATE SEAL)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
ANDREA SHERIDAN ORDIN
County Counsel

APPROVED AS TO CONTRACT
ADMINISTRATION:

Department of Public Health

By _____
Patricia Gibson, Chief
Contracts and Grants Division

#02031 BL

EXHIBIT A

LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER

**HUMAN IMMUNODEFICIENCY VIRUS (HIV)/
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
NON-OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE
PROPHYLAXIS SERVICES AGREEMENT**

1. DESCRIPTION: The Los Angeles County Non-Occupational Post-exposure Prophylaxis (nPEP) Program is an effort to provide an evidence-based, biomedical intervention as a component of a comprehensive package of HIV prevention services. nPEP after sexual exposure to HIV is recommended by the Centers for Disease Control and Prevention (see <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>) and the California State Office of AIDS.

A. The Los Angeles Gay & Lesbian Center, Sexual Health Program, (hereto referred as the "Contractor") will serve as a clinical site where clients will present for and receive nPEP services. CDC's guidelines recommend nPEP services must begin within seventy-two (72) hours post-exposure and the period of treatment with antiretroviral medications to be no less than twenty-eight (28) days to be considered efficacious.

B. Eligible clients will be subject to treatment activities such as clinical and laboratory evaluation; screening for HIV and other Sexual Transmitted Diseases (STD); treatment adherence counseling; and HIV counseling and risk-reduction.

C. Appropriate referrals services for intensive risk reduction counseling and other referral services will be provided free of charge and on a confidential or anonymous basis.

D. Clinicians should evaluate risks and benefits of nPEP on a case by case basis. For clients with exposure history that represent no substantial risk for HIV transmission or who seek care more than seventy-two (72) hours after exposure, the U.S. Department of Health and Human Services (DHHS) does not recommend use of nPEP.

2. PERSONS TO BE SERVED: nPEP services are targeted for delivery to HIV negative individuals who have had a high risk exposure to HIV. Clients seen through the Medical Outpatient Clinic and Sexual Health Clinics are eligible to receive nPEP services. For more specific guidelines on who is eligible for nPEP refer to the nPEP Manual of Procedures, Attachment III.

3. SERVICE DELIVERY SITE(S): Contractor's facilities where the nPEP services will be provided are located at: LAGLC, Sexual Health Program, 1625 North Schrader Boulevard, Los Angeles, CA 90028.

4. COUNTY'S MAXIMUM OBLIGATION:

A. During the period of Date of Board Approval through February 29, 2012, the portion of County's maximum obligation allocated under this Exhibit for nPEP services shall not exceed One Hundred Forty-Five Thousand, Four Hundred Twenty Seven Dollars (\$145,427).

B. During the of period March 1, 2012 through February 28, 2013, the portion of County's maximum obligation allocated under this Exhibit for nPEP

services shall not exceed Four Hundred Twelve Thousand, Eight Hundred Ninety-One Dollars (\$412,891).

5. COMPENSATION: County agrees to compensate the Contractor for performing services applicable to the nPEP after sexual exposure to HIV infection program as set forth in Schedules 1 and the BILLING AND PAYMENT Paragraph in the Agreement. Invoices and cost reports must be submitted and will be reimbursed in accordance with approved line-item detailed budgets.

6. SERVICES TO BE PROVIDED: During the term of this Agreement, the Contractor shall provide services in compliance with the nPEP Manual of Procedures, and delivery with fidelity the major program components. As a nPEP service delivery site, the Contractor and their designated staff shall fulfill the following services and delivery activities:

A. Participate with any in-service trainings including use of the nPEP Manual of Procedures and any other implementation components;

B. Focus on outreach efforts to HIV-negative clients who have had a high risk exposure to HIV. An outreach plan and all materials used for outreach activities and client education shall be approved by the Division of HIV and STD Programs (DHSP) sixty (60) days prior to use;

C. Conduct eligibility screenings to ensure that nPEP services are delivered to residents of Los Angeles County who are HIV-negative and who have had a high risk exposure to HIV and meet the program's inclusion criteria;

D. Provide nPEP services to a minimum of three hundred (300) clients following a treatment plan outlined in the nPEP Manual of Procedures;

E. Dispense and be accountable for nPEP antiretroviral medications consistent with the nPEP Manual of Procedures;

F. Provide clinical and laboratory evaluations consistent with the nPEP Manual of Procedures;

G. Provide nPEP medication adherence assessment and counseling consistent with the treatment consistent with the nPEP Manual of Procedures;

H. Provide HIV risk assessment and risk reduction counseling consistent with the nPEP Manual of Procedures; and

I. Maintain appropriate documentation, utilizing program case report forms and by laboratory testing results, and consistent with the nPEP Manual of Procedures to support delivery of services, program evaluation, and data collection.

J. The nPEP Manual of Procedures may be updated as necessary to ensure that the nPEP program is in compliance with State and Federal Guidelines as they relate to nPEP and/or to incorporate findings from ongoing program evaluation. The nPEP Manual of Procedures may also be updated or modified as data from the PQUAD demonstration project is analyzed and reported.

K. County reserves the right to add/delete specific tasks throughout the term of this Contract. Contractor shall be notified of any additions, deletions or changes. No addition to, or alteration of, the terms of this Contract, whether by written or verbal understanding of the parties, their officers, agents or employees, shall be valid unless made in the form of a written amendment to this Contract.

7. CLIENT/PATIENT ELIGIBILITY: Contractor shall be responsible for implementing client eligibility criteria. Services provided through the nPEP program are targeted to HIV negative individuals who have experienced a high risk HIV exposure..

A. Contractor will ensure that clients meet the program's inclusion criteria.

The following are the screening criteria for guiding client inclusion:

(1) A residents of Los Angeles County;

(2) Experienced a high risk exposure characteristics: one or more of the below, unprotected or with failed condom use:

(a) Receptive anal intercourse;

(b) Insertive anal intercourse;

(c) Receptive vaginal intercourse;

(d) Insertive vaginal intercourse;

(e) Receptive oral intercourse with intraoral ejaculation with known HIV positive source (supersedes all "high-risk source" criteria below);

(f) Sharing injection drug works, which have been intravascular

(g) Other exposures not listed above should be screened; and eligibility determined by the Contractor's Medical Director on a case by case basis.

(3) High risk source characteristic:

(a) Known HIV positive;

(b) Men who have sex with men (MSM);

- (c) Men who have sex with men and women (MSM/W);
 - (d) Intravenous drug use (IDU);
 - (e) Commercial sex worker (CSW);
 - (f) Sexual assault perpetrator;
 - (g) History of incarceration;
 - (h) From an endemic country (prevalence > 1%);
 - (i) Partner of one of the above;
- (4) Exposure within 72-hours of presentation;
 - (5) Not known to be HIV positive;
 - (6) No countermanding concomitant medications or allergies.

If the above inclusion criteria are met delivery of nPEP services can begin.

8. STAFFING REQUIREMENTS: Contractor shall establish a staffing plan consistent with the nPEP program's Manual of Procedures, described in Attachment III, to include the following requirements: a State of California licensed physician, a nurse practitioner, and an HIV prevention program manager.

A. Contractor will ensure staff is knowledgeable of target population; culturally and linguistically competent; knowledgeable of HIV, AIDS, and STDs; and knowledgeable of available community referral services, at a minimum.

B. Contractor shall ensure compliance with the above staffing requirements unless variations have been reviewed and approved by DHSP. When variations have been reviewed and approved, Contractor staff shall be supervised by appropriate professional/licensed personnel.

9. STAFF DEVELOPMENT AND TRAINING REQUIREMENTS: Contractor will maintain a plan for on-going staff training and development as an essential component to build staff capacity. nPEP Program Manager shall provide an orientation to the nPEP program for new workers and on-going supervision to ensure that the nPEP intervention is clearly understood.

10. CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS AND AGREEMENTS: County has the absolute right to approve or disapprove all of Contractor's subcontractor/consultants performing work hereunder and any proposed changes in Sub-contractor. Contractor shall obtain approval of DHSP Director prior to signing any subcontractor/consultant agreement and shall give DHSP Director thirty (30) days prior notice to review proposed subcontract or consultant agreement pursuant to Subsection (Subcontractor/Consultant Agreements) below:

A. Subcontractor/Consultant Agreements: Contractor shall adhere to this provision, and those of the Contract and Additional Provisions, for all subcontractor/consultant agreements entered into for the provision of services under this Contract. The proposed subcontractor/consultant agreement must include, but is not limited to, the name of the subcontractor/consultant, period of performance, description of activities that support the goals and objectives of the contract, an evaluation mechanism and itemized budget.

(1) Contractor must submit a copy of the proposed agreement within thirty (30) business days, prior to beginning services, for the approval of the DHSP Director.

(2) Subcontractor/consultant charges must be approved in advance of the start of the agreement by the DHSP Director or his/her designee.

(3) Subcontractor shall remove and replace personnel performing services under this Contract within thirty (30) days of the written request of the County. Contractor shall send County written confirmation of the removal of the personnel in question.

11. MATERIALS, AND SUPPLIES, AND EQUIPMENT: The purchase of all materials, and/or supplies, to provide the applicable services under this contract is the responsibility of the Contractor. Contractor shall use materials, and/or supplies that are safe for the environment and safe for use by the employee. Such materials, and/or supplies, etc., must have been clearly identified in the program budget and must have been approved in advance by the DHSP Director in order to be eligible for cost reimbursement.

In no event shall the County be liable or responsible for payment for materials and/or supplies purchased absent the required prior written approval.

Any and all materials and/or supplies purchased under this Contract are the property of County and must be returned to County in good working order at the end of the Term of the Contract.

Contractor shall provide DHSP with an annual list of equipment purchased through this Contract and at the written request DHSP.

12. EQUIPMENT PURCHASE: All equipment to be reimbursed by this Agreement must be pre-approved by the DHSP. Equipment purchase applies to the

Contractor and any subcontractors. The justification for the purchase should include how many clients will benefit from the purchase of the equipment during each budget period. For the purpose of this Agreement, Equipment is defined as an item with a unit cost of Five Thousand Dollars (\$5,000) or more and a life expectancy of four (4) or more years.

13. PROGRAM RECORDS: Contractor shall maintain adequate client clinical and laboratory testing records that supports the program's delivery of services and shall be current and kept in detail consistent with the nPEP Manual of Procedures, and good medical and professional practice in accordance with the California Code of Regulations. Client records shall include, but are not limited to the following case report forms:

- A. Week 1: Intake evaluation form;
- B. Week 2: Telephone evaluation form;
- C. Week 3: Source information form (if relevant);
- D. Week 4-6: Evaluation form;
- E. Week 12: Evaluation form;
- F. Week 24: Evaluation form.

14. REPORTS: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following report(s):

- A. Monthly Reports: As directed by DHSP, Contractor shall submit a signed hard copy of the monthly report and, as requested, the electronic format of the report and the STANDARD CLIENT LEVEL REPORTING Data for benefits

specialty services no later than thirty (30) days after the end of each calendar month. The reports shall clearly reflect all required information as specified on the monthly report form and be transmitted, mailed, or delivered to Division of HIV and STD Programs, 600 South Commonwealth Avenue, 10th Floor, Los Angeles, California 90005, Attention: Financial Services Division, Chief.

B. Semi-annual Reports: As directed by DHSP, Contractor shall submit a six (6)-month summary report of the client-level data collected through this program in hard copy, electronic, and/or online format for the periods.

C. Annual Reports: As directed by DHSP, Contractor shall submit a summary of data in hard copy, electronic, and/or online format for the calendar year due by the end of February of the following year.

D. As directed by DHSP, Contractor shall submit other monthly, quarterly, semi-annual, and/or annual reports in hard copy, electronic, and/or online format within the specified time period for each requested report. Reports shall include all the required information and be completed in the designated format.

15. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of services, and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening", attached hereto and incorporated herein by reference. Director shall notify

Contractor of any revision of these Guidelines, which shall become part of this Agreement.

16. SCREENING FOR SEXUALLY TRANSMITTED DISEASES: -Contractor shall conduct Screening for Sexually Transmitted Diseases as outlined in the nPEP Manual of Procedures.

17. TUBERCULOSIS CONTROL: Contractor shall adhere to Exhibit D, "Tuberculosis Exposure Control Plan for Medical Outpatient Facilities" as provided by the Los Angeles County Department of Health Services' Tuberculosis Control Program, attached hereto and incorporated herein by reference. Director shall notify the Contractor of any revision of this Plan, which shall become part of this Agreement.

18. EMERGENCY AND DISASTER PLAN: Contractor shall submit to DHSP within thirty (30) days of the execution of this Agreement an emergency and disaster plan, describing the procedures and actions to be taken in the event of an emergency, disaster, or disturbance in order to safeguard Contractor's staff and recipients of services from Contractor. Situations to be addressed in the plan shall include emergency medical treatment for physical illness or injury of Contractor's staff and recipients of services from Contractor, earthquake, fire, flood, resident disturbance, and work action. Such plan shall include Contractor's specific procedures for providing this information to all program staff.

19. EMERGENCY MEDICAL TREATMENT: Clients receiving services hereunder who require emergency medical treatment for physical illness or injury shall be transported to an appropriate medical facility. The cost of such transportation as well as the cost of emergency medical care shall not be a charge to nor reimbursable

hereunder. Contractor shall have a written policy(ies) for Contractor's staff regarding how to access Emergency Medical Treatment for recipients of services from the Contractor's staff. Copy(ies) of such written policy(ies) shall be sent to County's Department of Public Health, Division of HIV and STD Programs, Office of the Medical Director.

20. PEOPLE WITH HIV/AIDS BILLS OF RIGHTS AND RESPONSIBILITIES:

Contractor shall adhere to all provisions within Exhibit E, "People with HIV/AIDS Bill of Rights and Responsibilities" ("Bill of Rights") document attached hereto and incorporated herein by reference. Contractor shall post this document and/or Contractor-specific higher standard at all Care Services provider sites, and disseminate it to all patients/ clients. A Contractor-specific higher standard shall include, at a minimum, all provisions within the "Bill of Rights". In addition, Contractor shall notify and provide to its officers, employees, and agents, the "Bill of Rights" document and/or Contractor-specific higher standard.

If Contractor chooses to adapt this "Bill of Rights" document in accordance with Contractor's own document, Contractor shall demonstrate to DHSP, upon request, that Contractor fully incorporated the minimum conditions asserted in the "Bill of Rights" document.

21. COUNTY'S COMMISSION ON HIV: Contractor shall actively view the County's Commission on HIV (Commission) website <http://www.hivcommission-la.info/> and where possible participate in the deliberations, hard work, and respectful dialogue of the Commission to assist in the planning and operations of HIV/AIDS care services in Los Angeles County.

22. HOURS OF OPERATION: Contractor shall be required to deliver nPEP Services during the business hours, 11:00 a.m. through 8:00 p.m., on all weekdays (Monday through Friday) except those designated as holidays as noted below.

Contractor is not required to work on the following County recognized holidays: New Year's Day; Martin Luther King's Birthday; Presidents' Day; Memorial Day; Independence Day; Labor Day; Columbus Day; Veterans' Day; Thanksgiving Day; Friday after Thanksgiving Day; and/or Christmas Day and those designated as holidays per the Contractors Institutionally approved holidays .

23. CULTURAL COMPETENCY: Program staff should display non-judgmental, culture-affirming attitudes. Program staff should affirm that clients of ethnic and cultural communities are accepted and valued. Programs are urged to participate in an annual self-assessment of their cultural proficiency.

The nPEP program and its services are designed to be easily accessible; independent of ability to pay; non-judgmental; and culturally, ethnically, and linguistically appropriate to the target populations and the community-based clinical sites. Contractor staff shall incorporate these ideals during all nPEP delivery activities. It is recommended that the Contractor participate in an annual self-assessment of their cultural proficiency to perform appropriately clinical services relevant to nPEP.

SCHEDULE 1

LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER

HUMAN IMMUNODEFICIENCY VIRUS (HIV)/ ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) NON-OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE PROPHYLAXIS SERVICES AGREEMENT

	<u>Budget Period</u> Date of Board Approval through <u>February 29, 2012</u>
Salaries	\$ 32,250
Employee Benefits	\$ 6,894
Travel	\$ 0
Equipment	\$ 0
Supplies	\$ 75,075
Other Costs (Consultants/Contractual)	\$ 25,484
Indirect Cost*	<u>\$ 5,724</u>
TOTAL PROGRAM BUDGET	\$145,427

During the term of this Agreement, any variation to the above budget must have prior written approval of the Division of HIV and STD Programs's Director. Funds shall only be utilized for eligible program expenses. Invoices and cost reports must be submitted and will be reimbursed in accordance with approved line-item detailed budgets.

SCHEDULE 2

LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER

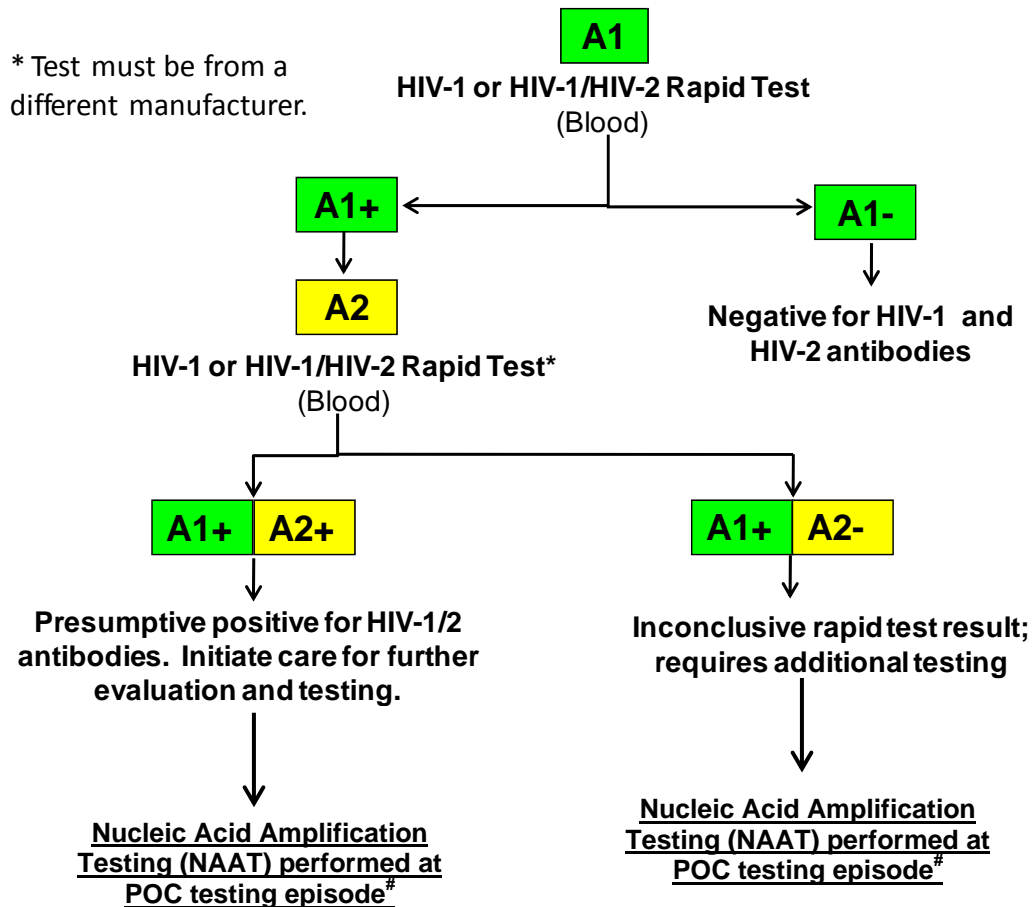
HUMAN IMMUNODEFICIENCY VIRUS (HIV)/ ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) NON-OCCUPATIONAL HUMAN IMMUNODEFICIENCY VIRUS POST-EXPOSURE PROPHYLAXIS SERVICES AGREEMENT

	<u>Budget Period</u> March 1, 2012 through <u>February 28, 2013</u>
Salaries	\$ 96,367
Employee Benefits	\$ 20,600
Travel	\$ 0
Equipment	\$ 0
Supplies	\$225,223
Other Costs (Consultants/Contractual)	\$ 53,597
Indirect Cost*	<u>\$ 17,104</u>
TOTAL PROGRAM BUDGET	\$412,891

During the term of this Agreement, any variation to the above budget must have prior written approval of the Division of HIV and STD Programs's Director. Funds shall only be utilized for eligible program expenses. Invoices and cost reports must be submitted and will be reimbursed in accordance with approved line-item detailed budgets.

Recommendations for Two-test HIV Rapid Testing Algorithms

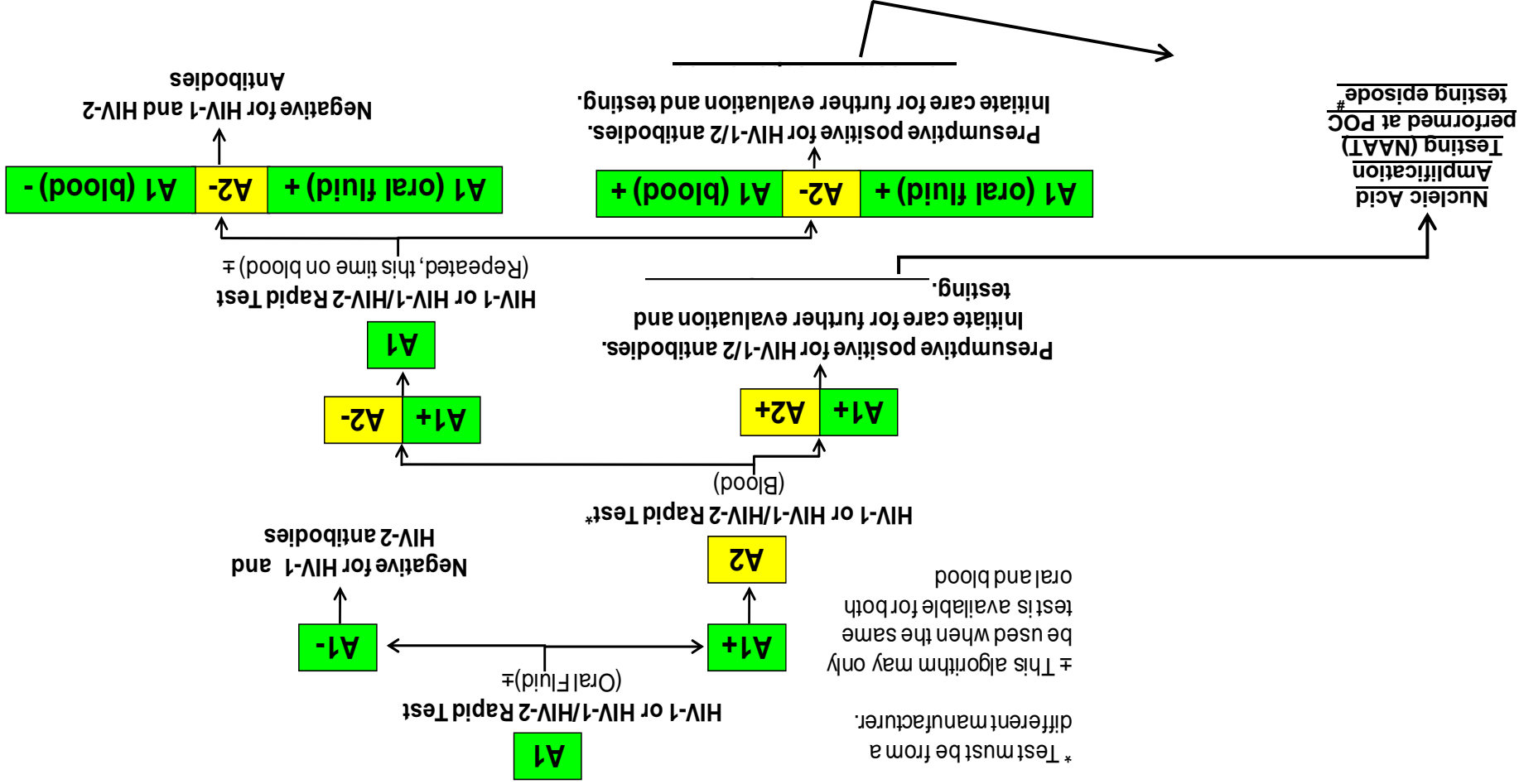
Figure 1. Two-test HIV rapid test algorithm with a blood screening test



Western blot testing may be performed in addition to/ in place of NAAT as specified in site specific HIV testing QA plan

Data Source: Adopted from HIV Testing Algorithms: A Status Report, point-of-care algorithm 2. Available at <http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIVStatusReport.aspx>

Figure 2. Two-test HIV rapid test algorithm with an oral specimen screening test



PEP-LA
LOS ANGELES COUNTY
NON-OCCUPATIONAL
HIV
POST-EXPOSURE
PROPHYLAXIS (nPEP)
PROGRAM

Manual of Procedures

2011



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ACRONYMS

MOP	Manual of Procedures
CDC	Center for Disease Control and Prevention
HCW	Health Care Worker
MSM	Men Who have Sex with Men
MSM/W	Men Who have Sex with Men/Women
IDU	Injection Drug Use
CSW	Commercial Sex Worker
SOP	Standing Operating Procedure
NAAT	Nucleic Acid Amplification Testing
HCG	Human Chorionic Gonadotropin
LAC	Los Angeles County
PHL	Public Health Laboratory
ED	Emergency Department
PO BID	By Mouth, Twice a Day
RNA	Ribonucleic Acid (same as viral load)
STI	Sexually Transmitted Infection
ELISA	Enzyme-Linked Immunosorbent Assay
AHI	Acute HIV Infection
CMR	Confidential Morbidity Report
TP-PA	Treponema Pallidum Particle Agglutination
RPR	Rapid Plasma Reagin
RIBA	Recombinant Immunoblot Assay
CDPH	California Department of Public Health
STD	Sexually Transmitted Disease
USC	University of Southern California
UCLA	University of California Los Angeles
APLC	Asian Pacific Liver Center
HCV	Hepatitis C Virus
CM	Contingency Management
OAPP	Office of AIDS Programs and Policy
RAI	Receptive Anal Intercourse
IAI	Insertive Anal Intercourse
RVI	Receptive Vaginal Intercourse
IVA	Insertive Vaginal Intercourse
SART	Sexual Assault Response Teams

INTRODUCTION TO THE PEP-LA MANUAL OF PROCEDURES

Welcome to the PEP-LA Program. This **Manual of Procedures** (MOP) is intended for use as a guidance document and training tool for all sites implementing post-exposure prophylaxis for non-occupational exposure to HIV (nPEP) within Los Angeles County (LAC). It provides an overview of nPEP and operational instructions for delivering all of the site-specific components of the program and clinical services, including screening for eligibility; clinical and laboratory evaluation; drug and sexual risk assessments; behavioral risk reduction programming, timing of follow-up evaluation; and data management.

Resources

For additional information on nPEP, please refer to the following recommendations from the Centers for Disease Control and Prevention (CDC) and the State of California Office of AIDS

- <http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf>
- <http://www.cdph.ca.gov/programs/aids/Documents/RPT2004OfferingPEPFollowingNonOccupExp2004-06.pdf>

Or contact:

Rita Marmolejo, Program Manager
Division of HIV and STD Programs
Care Services Division
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rmarmolejo@ph.lacounty.gov

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Care Services Division

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Gary P. García, MPH, Technical
Assistance
Division of HIV and STD Programs
Office of the Medical Director
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gagarcia@ph.lacounty.gov

SECTION 1: PROGRAM OVERVIEW

1.0 What is nPEP?

There is no cure for HIV. The most effective methods of preventing HIV infection are to prevent exposure through reduced sexual risk behavior, consistent condom use, injection drug use abstinence, and consistent use of sterile injection

equipment. Comprehensive HIV prevention strategies include both behavioral risk-reduction and biomedical interventions.

Los Angeles County HIV prevention programming is comprised of a range of evidence based prevention services of which biomedical HIV prevention interventions can be an integral component. These services are designed to be easily accessible, non-judgmental, culturally, ethnically, and linguistically appropriate to the relevant populations, community-based, and independent of ability to pay or insurance/documentation status.

Non occupational Post-Exposure Prophylaxis (nPEP) is an HIV preventative service provided to HIV-uninfected persons to reduce the likelihood of HIV infection after a high-risk sexual or injection drug use exposure. HIV Post-exposure prophylaxis is a 28-day course of antiretroviral therapy initiated as soon as possible, but within 72 hours after a high-risk exposure. HIV Post-exposure prophylaxis is recommended by the CDC and the California State Office of AIDS.^{1,2,3} HIV Post-exposure prophylaxis for *occupational* exposures to health-care workers (HCW) has been demonstrated in a single case-control study to reduce the odds of acquiring HIV after a needle stick injury from an HIV-positive source patient by 81% (OR 0.19, 95% CI 0.06 to 0.52).⁴ The baseline risk of acquiring HIV after a needle stick injury from an HIV-positive source patient is approximately 0.3%. Table 1 references estimated risks of HIV transmission

¹ California Task Force on Non-Occupational PEP and the California Department of Health Services Office of AIDS. Offering HIV post-exposure prophylaxis (PEP) following non-occupational exposures: Recommendations for health care providers in the state of California. (Sacramento, CA, 2004).

² Centers for Disease Control and Prevention. Antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. In *MMWR Recommendations and Reports Vol 54 No. RR-2* (2005).

³ Centers for Disease Control and Prevention. Updated US public health service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. In *MMWR Recommendations and Reports Vol 54 No. RR-9* (2005).

⁴ Cardo, D.M., *et al.* A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. *N Engl J Med* **337**, 1485-1490 (1997).

⁵ Pinkerton, S.D., *et al.* Cost-effectiveness of HIV postexposure prophylaxis following sexual or injection drug exposure in 96 metropolitan areas in the United States. *Aids* **18**, 2065-2073 (2004).

⁶ Herida, M., *et al.* Cost-effectiveness of HIV post-exposure prophylaxis in France. *AIDS* **20**, 1753-1761 (2006).

associated with various types of *non-occupational* exposures. HIV post-exposure prophylaxis has been demonstrated to be safe, feasible, and cost-effective if appropriately targeted.^{5,6}

Table 1. Estimated per-act risk for acquisition of HIV, by exposure route*		
Exposure Route	Risk per 10,000 exposures to an infected source	Reference
Blood Transfusion	9,000	74
Needle-sharing injection-drug use	67	75
Receptive anal intercourse	50	76,77
Percutaneous needle stick	30	78
Receptive penile-vaginal intercourse	10	76,77,79
Insertive anal intercourse	6.5	76,77
Insertive penile-vaginal intercourse	5	76,77
Receptive oral intercourse	1	77 ⁺
Insertive oral intercourse	0.5	77 ⁺

*Estimates of risk for transmission from sexual exposures assume no condom use

+ Sources refers to oral intercourse performed on a man

Centers for Disease Control and Prevention. Antiretroviral post-exposure prophylaxis after sexual, injection drug use, or other non-occupational exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. In *MMWR Recommendations and Reports Vol 54 No. RR-2* (2005).

1.1 Where will PEP-LA be made available?

Initial Program sites are:

Los Angeles Gay and Lesbian Center
Sexual Health Program
1625 N. Schrader Boulevard
Los Angeles, CA 90028
(323) 993-7400

MLK-MACC
OASIS Clinic
1807 E 120th Street
Los Angeles, CA 90059
(310) 668-4213

1.2 To Whom Will Services be Provided?

The Program is designed for the highest-risk sexual exposures. Therefore, services will be provided to those individuals meeting the following criteria:

To receive services, a patient must have no form of public or private health insurance that covers nPEP services and medications. If a patient presents for nPEP with any form of health insurance, the nPEP coordinator will telephone the insurance company with the patient, to determine if PEP medications and services are covered.

Patients must be at least 18 years of age.

- *High-Risk Exposure Characteristic* (one or more of the below, unprotected or with failed condom use)
 - Receptive Anal Intercourse (RAI)
 - Insertive Anal Intercourse (IAI)
 - Receptive Vaginal Intercourse (RVI)
 - Insertive Vaginal Intercourse (IVA)
 - Receptive Oral Intercourse with Intraoral Ejaculation with **known HIV+ source**
 - Sharing injection drug works, which have been intravascular
 - Other exposures not listed above should be screened and eligibility determined by the on site Medical Director on a case by case basis
- *High-Risk Source* (one or more of the below)
 - Known HIV positive
 - MSM
 - MSM/W
 - IDU
 - CSW
 - Sexual assault perpetrator
 - History of incarceration
 - From an endemic country (prevalence >1%)
 - Partner of one of the above
- *Exposure within 72 hours of presentation*
- *Not known to be HIV positive*

➤ *No countermanding concomitant medications or allergies*

1.3 How Will Patient Information be Collected?

Patient information will be collected through completion of evaluation forms uniquely designed for this program. The evaluation forms are:

- Intake Evaluation Form
- 2 Week Telephone Evaluation Form
- 4-6, 12, and 24 Week Evaluation Form
- Source Information Evaluation Form

The evaluation forms can be found in the appendix of this document. Additionally, the sites will use the OAPP Routine Testing Form for 4-6, 12, and 24 Week follow-up.

1.4 The PEP-LA Warmline

The Program will utilize a Warmline to support access to services. The Warmline is managed from the Office of AIDS Programs and Policy and is designed as an entry port for potential patients. The Warmline is operationalized as a “telephone-tree,” meaning that callers seeking service information via the Warmline will have the option of having their call automatically directed to either of the Program sites. The Program sites will be required to maintain a dedicated PEP-LA telephone line, with voice message box, for purposes of receiving these directed outside calls. Refer to **Appendix P** for coordination of patient referral between sites.

The PEP-LA Warmline is: (213) 351-7699

Figure 1: Flow Chart for Initiation of nPEP

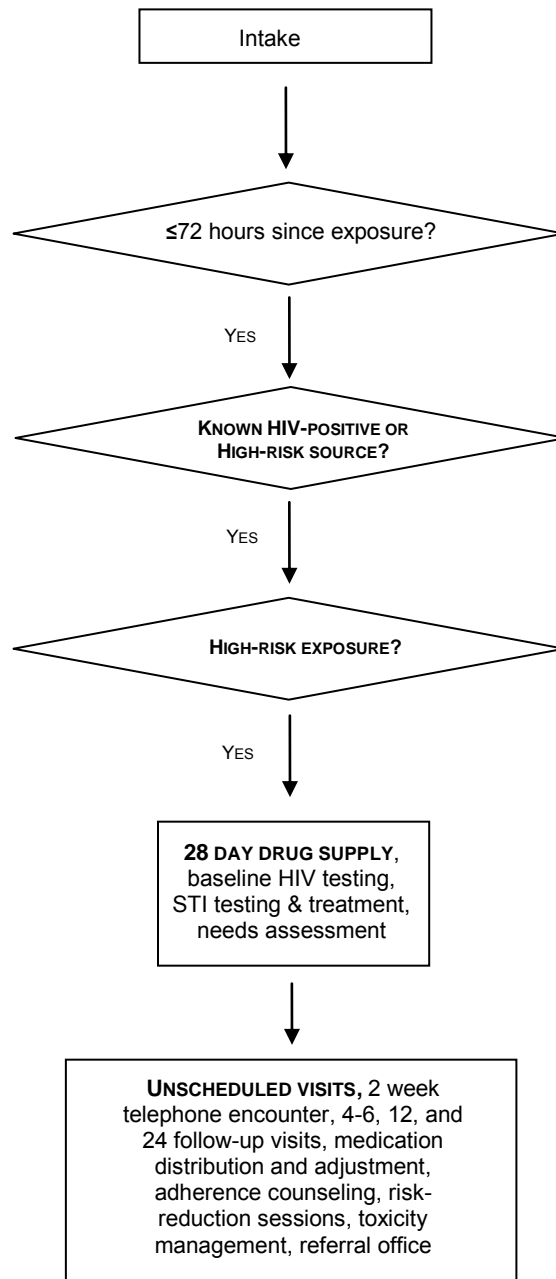


Table 2. Schedule of Clinical and Lab Evaluations and Other Assessments

	Intake Visit	Week 2 Telephone Encounter	Week 4-6 Visit	Week 12 Visit	Week 24 Visit
Risk Assessment					
Sex, Drugs and Alcohol	X		X	X	X
HIV Diagnostic					
HIV ELISA^c	X		X	X	X
HIV RNA to r/o AHI	X				
Stored HIV RNA and Genotype^d			X	X	X
STD Diagnostic					
Urine/vaginal GC/CT	X				
Rectal GC/CT	X				
Pharynx GC	X				
Serum RPR	X			X	
Urine HCG^a	X		X^b	X^b	
HBsAg	X				
HCV Antibody	X			X	
Safety Lab Diagnostic					
Cr, LFTs, CBC	X	X^b	X^b	X^b	X^b
Interventions					
Meds Dispensed	X				
Adherence Counseling	X	X			
Risk-Reduction Counseling (brief)	X	X	X	X	X
Referral to Services: (Intensive Risk-Reduction, Substance Abuse, Mental Health)	X^b	X^b	X^b	X^b	X^b
HIV/STI Partner Services - as needed	X		X	X	X
Hepatitis A and B Vaccination (if indicated)	X		X	X	X

^aFemales of childbearing potential only^bIf clinical and/or behavioral signs and symptoms direct, not routine^cPositive or indeterminate rapid HIV ELISA testing will be confirmed with a serum Western Blot^dSpecimens will be drawn and stored at the indicated time points. If HIV seroconversion occurs, these samples will be run for HIV RNA (viral load) and genotyping. These samples should be collected in sufficient amounts (refer to **section 3.2 Specimen Collection, Processing, Labeling, Storage, and Transport Procedures**) to permit **prospective** HIV RNA testing and genotyping. These labs will be couriered to the LAC PHL for storage. Appropriate tracking logs must be kept in order to permit future retrieval of samples for testing.

SECTION 2: nPEP PROGRAM DELIVERY

Table 2 outlines the schedule of clinical and laboratory evaluations and the assessments, counseling and referrals that are to be delivered as part of the nPEP program.

2.0 Patient Screening and Intake Evaluation

Screening for eligibility for nPEP is initiated in person. To initiate screening, a patient presents to one of the service delivery sites. Patients who call the LA County PEP-LA Warmline may be pre-screened on the phone (see above for Warmline information), however confirmation of eligibility and enrollment in the program must occur at the service delivery site. A screening of inclusion and exclusion criteria and the nPEP Intake Evaluation Form will be performed by program personnel. For those who meet the inclusion criteria the following intake evaluation steps will be met:

- directed history and physical examination conducted by a provider of care;
- conduct an HIV rapid test;
- order an HIV viral load test to assess acute HIV infection (Patients subsequently found to be acutely HIV positive via viral load testing will be discontinued from the program and linked to appropriate HIV care and treatment services);
- order baseline safety labs including: serum creatinine level to identify any underlying renal dysfunction and determine appropriate medication and dosing; liver function tests; and baseline complete blood count;
- order urine HCG testing for women of child bearing age/potential;
- order baseline Hepatitis B (Hep BsAg) and Hepatitis C (Hep C Antibody) screening;
- conduct STD screening (*non-treponemal* screening with reflex confirmatory *treponemal* test); urine and rectal gonorrhea (GC) and chlamydia (CT) Nucleic Acid Amplification Testing (NAAT); and oral GC NAAT;
- offer vaccination for Hepatitis A and/or B if patient reports no history of vaccination (no screening for immunity prior to vaccination required);
- conduct adherence counseling for nPEP medication and treatment regimen;
- conduct sexual and substance use risk assessment;
- conduct brief HIV risk-reduction counseling, including referral for further intensive risk-reduction intervention when appropriate;

- facilitate referral to LAC Partner Services program when *source* patient is known HIV+ or if patient seeking nPEP is diagnosed with sexually transmitted infection at *any point* during nPEP program; and
- elicit information on the *source* individual and complete Source Information Form [refer to **Section 2.4** and **Appendix D**]

Refer to nPEP Intake Form **Appendix A** to record this information. Also, refer to **Section 4.0** for specific information on laboratory based screening procedures.

At program intake, after collection of the risk assessment and delivery of brief risk-reduction counseling, all patients should be given the option to receive a referral to more intensive risk-reduction services, including behavioral and substance use, either through in-house programs, or externally to existing LAC HIV risk-reduction programming. Information for health education, mental health and substance abuse services within LAC can be found at www.hivla.org. [Refer to **Sections 7 and 8** for more information on risk assessments and risk-reduction counseling].

For specific information on medication and treatment adherence assessments and intervention [refer to **Section 9**].

2.1. Optimizing Time to nPEP Treatment for Eligible Patients

The success of nPEP to prevent HIV infection is dependent upon receiving services as soon as possible after exposure. Thus, nPEP program sites must establish clear protocols that take into account the time sensitive nature of the service. This includes standard operating procedures (SOP) [refer to **Appendix O** for procedures] that ensure the following:

- The time from initial patient inquiry/referral to the time the patient has been scheduled for a formal screening and intake should not exceed 3 hours. Patient inquiry/referral includes patient calls on the LA-PEP Warmline as well as patients presenting in person inquiring about nPEP services or referred from a provider.
- All telephone messages left at program sites from patients requesting services will be returned within one hour during clinic operating hours.
- After hours and weekend triage of patients to Emergency Department for evaluation for nPEP and “starter packs” or initial dose(s) of nPEP. This includes ensuring appropriate instructions are recorded on the nPEP voice message telephone line at the clinical site, which includes the hours of

operation of the clinic each day of the week, and instructs patients to go to an Emergency Department in LAC that offers nPEP if clinic is not open.

2.2 Patients Referred to the Program Already Initiated nPEP

Because of the time sensitive nature of nPEP, some patients may be given an initial dose or a “starter pack” with a small supply of antiretroviral medications when they are initially evaluated in an Emergency Department, or another clinical site, and then referred to the PEP-LA program. Starting nPEP at another site or with another provider does NOT preclude the patient from enrolling in the PEP-LA program provided they are eligible by LAC program inclusion criteria. Patients who are referred after starting nPEP elsewhere should be screened for eligibility for the PEP-LA program, and if they meet criteria, they should begin the intake process and procedures outlined within this manual of procedures. If the patient has started on a different nPEP medication regimen, the provider may change the regimen to the available nPEP regimen after assessment for any potential contraindications. However, because the PEP-LA program targets those with the highest risk exposures (consistent with CDC guidelines) if the patient does NOT meet the inclusion criteria outlined in **Section 1.3**, s/he should NOT be continued on nPEP through the PEP-LA program. Additionally if patients have had an interruption of medication for 72 hours or longer when they present for services, they will not be eligible to be continued as an enrollee on the program.

2.3 nPEP Medication Regimens

The preferred regimen for standard, high-risk exposures will be tenofovir and emtricitabine, provided as a fixed-dose combination tablet as Truvada®. Dosing of Truvada is 1 tablet by mouth once daily. For patients with a creatinine clearance 30-49 mL/min, dosing of Truvada is 1 tablet by mouth every 48 hrs. For patients with creatinine clearance <30 mL/min or on hemodialysis, Truvada should not be used. For intolerance to Truvada, pregnancy, or in the event of Truvada non-availability, Combivir (zidovudine 300mg + lamivudine 150mg) will be available to be taken as 1 PO BID (1 tablet by mouth twice a day). For patients with a creatinine clearance <50 mL/min, including those on hemodialysis, Combivir may be dose-adjusted to 1 tablet by mouth once daily. For specific information on medication and treatment adherence assessments and intervention [refer to **Section 9**].

Given the lack of data on superior efficacy of a 3- vs 2-drug nPEP regimen, and the significant cost associated with nPEP, the program will utilize a 2-drug nPEP regimen.

An exception to the program procedure to include an expanded 3-drug regimen of nPEP may be made *only* when there is established evidence of exposure to an NRTI resistant HIV virus from the source patient. All criteria listed below need to be met in order for a patient to receive an expanded 3-drug regimen:

- Known HIV+ source (documented by HIV ELISA, WB, or viral load)
- Genotype documenting major NRTI mutations conferring resistance to Truvada (or Combivir), or Phenotype demonstrating *in vitro* resistance to Truvada (or Combivir)

The 3rd drug to be added to the nPEP regimen will be at the discretion of the site Medical Director, based on the resistance pattern found in source patient.

If source resistance is known and documented, *expert HIV consultation should be sought, but ANY DELAY IN ADMINISTERING A FIRST DOSE OF AN “EXPANDED” 3-DRUG REGIMEN IS DISCOURAGED. The regimen may be adjusted subsequent to a first dose after consultation with experts. A reasonable 3-drug regimen would include the addition of a boosted protease inhibitor such as kaletra (ritonavir/lopinavir).*

In the event of toxicity, intolerance, or allergy, refer to Medication Toxicity Management, **Section 10**.

Missed dose instructions

A missed dose should be taken if the discovery of the missed dose is within 6 hours of the intended dose-time. If the discovery of the missed dose is longer than 6 hours from the intended dose-time, the dose should not be taken, and dosing resumed at the next intended dose-time. Doubling of dosing should not occur.

Duration of therapy

All regimens should be taken for 28 days. For participants who are on every-other-day dosing schedules, this may total fewer than 28 individual days on which medication doses are ingested, but will still compose 28 days of medication exposure from the date of first dosing PEP medications. Providers may dispense a 28-day supply to patients, or if there are concerns for toxicity or the need to more closely monitor the patient, the provider may chose to dispense a 14 day supply of nPEP and have the patient return for a 2 week visit and refill for additional 14

days. The quantity of medication dispensed to the patient (14 days or 28 days) will be left to the discretion of the provider and may vary according to the individual patients' treatment plans and needs.

2.4 Source Evaluation

The *source* is the individual to whom the nPEP patient reports being exposed. When at all possible, providers should work with nPEP patients to bring the *source* patient in to the clinical site for evaluation. If a *source* is available for testing, and is of unknown HIV-serostatus, the *source* should be offered HIV antibody testing (rapid testing, if available), and with rare exceptions, a negative test is sufficient evidence to recommend discontinuation of nPEP for the exposed patient.

If the *source* is available, and there is suspicion of the *source* having ongoing high-risk behavior such as recent (within the last 4-6 weeks) high-risk unprotected sexual contact or sharing of injection drug works, the *source* should additionally have HIV RNA testing; in such cases, nPEP of the exposed patient should be continued, and consultation with HIV treatment experts should be coordinated. For known HIV-positive *sources*, Hepatitis B and C status, if known should be documented.

If the *source* is not available, the exposed patient should be queried as to likely demographic parameters to help program personnel with risk stratification (i.e. MSM, IDU, CSW, endemic national, etc).^{7,8}

Data for the *source* should be recorded on [refer to nPEP Source Information Form **Appendix D**].

2.5 Patient Two-Week Evaluation

At the two week post-exposure follow-up, the patient evaluation is conducted by telephone by program personnel, unless otherwise instructed by the nPEP provider. The follow-up evaluation is designed with a suggested script for program personnel to:

- conduct a 4-day recall medication adherence assessment and counseling;
- conduct brief risk-reduction counseling;
- review any signs or symptoms experienced on medication regimen; and

- schedule an in-person appointment if any clinical symptoms or concerns are present, or there is need for additional adherence counseling or STI screening based on discussion with patient.

The “check-in” is the half-way point in the 28-day regimen and affords an opportunity to conduct brief risk reduction counseling and to assess whether the patient needs further clinical evaluation or other support. All symptoms and possible nPEP side effects should be reported to the clinical care provider with in person follow-up when appropriate. Examples of reasons for referral for an in-person visit with a clinician may include but are not limited to: adherence difficulty (> 2 missed doses of medication); side effects from nPEP regimen; and any signs or symptoms that may require medical evaluation (e.g. symptoms of STI or Acute HIV Infection, jaundice, change in color/quantity of urine, abdominal pain, nausea, vomiting, muscle aches, easy bruising/bleeding, etc.).

Data for the two-week evaluation should be recorded on the nPEP Program 2 Week Telephone Form [refer to **Appendix B**].

2.6 Patient 4-6 Week Evaluation

At 4-6 week post exposure follow-up, the patient will have completed the 28-day nPEP regimen. The evaluation is an in-person visit provided by the nPEP program personnel to:

- conduct a 4-day recall medication adherence assessment;
- conduct a rapid HIV test;
- collect banked serum to be stored at PHL (RNA/Genotype);
- conduct a follow-up substance use and sexual risk assessment; and
- conduct brief risk-reduction counseling.

As at program intake, nPEP patients should be offered a referral to more extensive substance use and risk reduction services if appropriate, either through in-house programs, or externally to existing LAC behavioral risk-reduction programming. Information for services in LAC can be found at www.hivla.org. For specific information on adherence assessments and interventions refer to **Section 9**.

Data for the 4-6 week evaluation should be recorded on the nPEP 4-6, 12, and 24 Week Form [refer to **Appendix C**].

2.7 Patient 12 Week Evaluation

At 12 week post exposure follow-up, the evaluation is an in-person visit provided by program personnel to:

- conduct a rapid HIV test (use Routine Testing Form);
- order a Hepatitis C test;
- order a syphilis test;
- collect banked serum to be stored at PHL (RNA/Genotype);
- conduct a follow-up substance use and HIV risk assessment; and
- conduct brief risk-reduction counseling.

As at program intake, nPEP patients should be offered a referral to more intensive substance use and risk reduction services if appropriate, either through in-house programs, or externally to existing LAC behavioral risk-reduction programming. Information for services in LAC can be found at www.hivla.org. For specific information on adherence assessments and interventions refer to **Section 9**.

At 12-week follow-up, a two week window before or after is appropriate for timing of follow-up, i.e. a visit between 10 and 14 weeks is acceptable practice.

Data for the 12 week evaluation should be recorded on [refer to nPEP Program 4-6, 12, and 24 Week Form **Appendix C**]. HIV testing information is recorded on the Routine Testing Form.

2.8 Patient 24 Week Evaluation

At 24 week post exposure follow-up, the evaluation is an in-person visit provided by program personnel to:

- conduct a rapid HIV test;
- collect banked serum to be stored at PHL (RNA/Genotype);
- conduct follow-up substance use and HIV risk assessment; and
- conduct a brief risk reduction counseling.

As at program intake, nPEP patients should be offered a referral to more intensive substance use and risk-reduction services if appropriate, either through in-house programs, or externally to existing LAC behavioral risk-reduction programming. Information for services in LAC can be found at www.hivla.org. For specific information on adherence assessments and interventions refer to **Section 9**.

At 24-week follow-up, a four week window, either way, is appropriate for timing of follow-up, i.e. a visit between 20 and 28 weeks is acceptable practice.

Data for the 24 week evaluation should be recorded on the nPEP Program 4-6, 12, and 24 Week Form [refer to **Appendix C**].

2.9 Staffing/Facility

Staffing

Having qualified trained staff that perform and supervise the various activities of the PEP-LA program is one of the most important factors for ensuring an effective and successful program. Key aspects of this element are: staff qualifications and responsibilities, and training requirements. The program sites will establish a qualified staffing plan to include, but not necessarily limited to, a State of California licensed physician, a nurse practitioner, an HIV risk-reduction counselor, and an HIV prevention program manager.

At a minimum, the delivery sites will ensure staff is knowledgeable of, the background rationale for HIV *non-occupational* post-exposure prophylaxis; the target population services are intended; HIV, AIDS, and STDs; and available and relevant community referral services.

The PEP-LA program and its services are designed to be easily accessible; independent of ability to pay; non-judgmental; and culturally, ethnically, and linguistically appropriate to the target populations and the community-based clinical sites. The program staff shall incorporate these ideals during all nPEP delivery activities. It is recommended that the program sites participate in an annual self-assessment of their cultural proficiency to perform appropriately delivered clinical services relevant to nPEP.

Additionally, the program sites will maintain a plan for on-going staff training and development as an essential component to build staff capacity. The program manager shall provide an orientation to the PEP-LA program for new staff and on-going supervision to ensure that the nPEP intervention is clearly understood and effectively delivered.

Phlebotomy

Laboratory and/or program staff will order and collect specimens according to the schedule outlined in **Table 2** and **Section 3**. All specimens will be collected by a

lab assistant (or equivalently trained and California State licensed clinician) with documented training and certification in phlebotomy; the handling, shipping and disposal of biohazardous materials/blood borne pathogens; and training in the procedures of rapid HIV testing.

Pharmacy

The program sites will develop a relationship with a pharmacy to ensure a durable and sustainable antiretroviral medication supply, and appropriate medication preparation and dispensing, to adequately delivery the nPEP services. An established pharmacy will operate within all applicable state and federal laws; regulations; and licensure requirements, including all policies for an appropriately trained staff. The program is currently approved to dispense an nPEP 2-drug regimen of either Truvada (TDF/FTC) or Combivir (AZT/3TC).

SECTION 3: HIV TESTING

3.0 Rapid HIV Testing

Rapid ELISA testing will be used (oral transudate, finger stick, or phlebotomized blood). All positive or indeterminate rapid results will be confirmed by serum Western Blot testing. HIV rapid testing will be conducted at intake, as well as at 4-6, 12, and 24 week visits.

3.1 HIV Viral Load

All patients enrolled in the nPEP program and who have a negative rapid ELISA HIV test will have blood drawn for HIV viral load testing. The viral load test will be sent to the Los Angeles County Public Health Laboratory (LAC PHL) to evaluate for acute HIV infection. HIV viral load results will be reported directly to the provider. In the event of a positive viral load, the nPEP patient should be telephone called immediately, instructed to discontinue nPEP, and referred to an expert HIV-provider for confirmation and further clinical management.

3.2 Stored Samples for HIV RNA and Genotype Testing

The program will collect HIV RNA and Genotype specimens at each in-person follow-up visit to store at the LAC PHL. In the occurrences of an observed and documented seroconversion, all stored specimens of the patient's plasma will be run for HIV RNA, and where viral load is detected, an HIV Genotype will also be run on that specific specimen. The rationale for this retrospective evaluation is to

approximate a time frame for the observed seroconversion. These specimens should be collected in sufficient amounts as referenced below. Each program site should maintain appropriate logs to track specimens sent to PHL [refer to **Appendix G**] for placement in storage [refer to **Appendix F**]. The Division of HIV and STD Program will request the tests upon being notified by the nPEP Site of a seroconversion.

Processing instructions for stored RNA/Genotype specimens:

Test Name	Specimen/Storage/Transport	
HIV-1 Viral Load	Collect specimen in K2 EDTA tube. Centrifuge at 800 – 1660 g for 20 minutes at RT. Transfer plasma to sterile polypropylene tube. Freeze and deliver to PHL frozen on dry ice. 5 ml for both tests.	Viral Load specimen minimum 3 ml.
HIV-1 Genotype		Resistance (Genotyping) specimen minimum 2 ml.

3.3 Triage of Exposed Patients

Before administration of first doses of nPEP, HIV-testing will be performed by rapid HIV-testing and viral load testing as outlined previously. If the patient tests HIV-positive on the rapid test, nPEP should NOT be delivered and the patient should be referred to an expert HIV provider for confirmatory testing and clinical management for HIV.

If the exposed patient is determined to be HIV-negative by rapid testing, the nPEP services may begin. To identify patients experiencing acute HIV infection at baseline, an HIV viral load test will be conducted at the LAC PHL for each nPEP patient enrolled. Test results are reportable by PHL in approximately 3-5 days and will be reported directly to the clinical sites. In the event of detectable viral load, the nPEP patient should be telephone called immediately, instructed to discontinue nPEP, and referred to an expert HIV-provider for confirmation and further clinical management.

3.4 Exposed Patients Who are not Eligible or Decline nPEP

In the event a patient is not eligible or declines nPEP, rapid HIV testing should still be offered, brief risk-reduction counseling provided, and referral to other services

should be made for longitudinal follow-up HIV testing at a linguistically, culturally, and financially appropriate primary-care setting.

SECTION 4: ADDITIONAL LABORATORY TESTING

4.0 STI Screening

Screening for STIs is a significant preventative service provided as a component of the nPEP program. All STI tests are sent to the LAC PHL for processing. Treatment of positive results will be delivered at the program sites and reported to the LAC Sexually Transmitted Disease Program (refer to **Appendix J** for CMR for STD reporting). Please refer to LAC PHL lab order form in **Appendix H** for additional detail on how to order STD testing.

Gonorrhea and Chlamydia Testing

All patients will be screened site specific at intake evaluation with NAAT for *N. gonorrhoeae* (GC) pharyngeal, rectal, and urine/vaginal, and *C. trachomatis* (CT) for urine and rectal. Rectal samples will be self-administered by patients [refer to **Appendix I** Instructions for the Self-Collection of a Rectal Swab]. Pharyngeal screening for GC will be collected from patients by throat swabbing. Subsequent GC/CT screening will be conducted at follow-up if directed by symptoms or history of possible exposure.

Syphilis Testing

All patients will be screened at intake for *T. pallidum* (syphilis) by serum RPR testing, with a reflex TP-PA confirmatory test (if no prior history of syphilis) and RPR titer, as is routinely conducted by the LAC PHL. If patients have a history of syphilis, then serum RPR titer is indicated. Repeat testing for serum RPR will be performed at the Week 12 visit to assess for incubating syphilis acquired at the time of the initial exposure. Additional syphilis screening will be conducted at follow up evaluation if directed by symptoms or history of exposure.

4.1 Hepatitis B and C Screening

Screening for Hepatitis B infection with the Hepatitis B surface antigen, and Hepatitis C with the Hepatitis C antibody will be performed at intake. Given the recent reports of sexually transmitted Hepatitis C among HIV-positive MSM, Hepatitis C antibody testing will be performed again at the week 12 visit. The main reason for screening for those at increased risk is to determine if they are infected in order to refer to medical care. If Hepatitis B Antigen or Hepatitis C

antibody tests are positive, patients should be confirmed with a HBV viral load (HBV DNA), or HCV viral load (HCV RNA), to confirm chronic infection. Refer to **Section 5.3** for further information on procedures for treatment referral for patients testing positive for Hepatitis B or C.

4.2 Pregnancy

Women of childbearing potential will be tested for pregnancy by urine hCG at intake, and as clinically indicated throughout the 6 months of follow-up. A positive result should trigger utilization of the nPEP Protocol for Treatment of Pregnant Women and consultation with HIV treatment experts [refer to **Section 11** for more information].

4.3 Serum Creatinine

Serum creatinine will be ordered and evaluated at intake to determine appropriate medication dosing, and then only in symptom-directed fashion subsequently.

4.4 Liver Function

AST [SGOT], ALT [SGPT], total bilirubin, and alkaline phosphatase will be ordered and evaluated at intake and then only in symptom-directed fashion subsequently.

4.5 Complete Blood Count

Hemoglobin, hematocrit, white blood cell count [WBC], differential, and platelet count will be ordered and evaluated at intake and then only in symptom-directed fashion subsequently.

SECTION 5: STI TREATMENT, HEPATITIS VACCINATION, AND TREATMENT REFERRAL

5.0 STI Treatment

As a comprehensive package of nPEP services, all patients with positive screening tests for gonorrhea, chlamydia, and/or syphilis should be treated at the nPEP service delivery site. A summary of STD treatment guidelines from the California Department of Public Health (CDPH) and CDC are available at:

- http://publichealth.lacounty.gov/std/docs/CA_STDTreatmentGuidelines2010.pdf,
- <http://www.cdc.gov/std/treatment/2010/>.

5.1 Hepatitis A and B Vaccination

Hepatitis A and B vaccinations should be offered to patients who have no history of vaccination and are in the below-referenced target populations.

Refer to the following CDC web site and MMWR (February 2011) regarding adult immunization schedule, including guidance for Hepatitis A and B vaccination.

- <http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm>

Hepatitis A and B Vaccination

- Men who have sex with men
- Injection drug users or non-injection illicit drug users
- Persons with chronic liver disease (including Hep B or C infection)
- Persons traveling to countries with high or intermediate endemic rates of Hepatitis A
- Persons with HIV-infection
- Any person who would like to be vaccinated for Hepatitis A

Within LAC, patients have several options available for free or low cost Hepatitis A and B vaccination. Patients who are vaccinated as a part of the nPEP program and who require follow up vaccine doses may telephone the STD Hotline at **1(800)758-0880** for information on where to receive free or low cost vaccination services. A list of these sites is also provided within **Appendix L**.

Additional resources for free or low cost vaccination are as follows:

1. AIDS Healthcare Foundation (AHF) Men's Wellness Center
2. LA Gay and Lesbian Center (LAGLC) Sexual Health Program
3. LAC STD / Immunization Clinics. Be sure to call ahead for immunization clinic hours and to make sure they have adult hepatitis A and /or B vaccine available [**Appendix L**].
4. Visit **www.HIVLA.org** and enter the keyword “vaccination” for more information on community clinics in LAC that offer vaccine.
5. Attend a **HepTeamLA** event during the summer months (to find out which pride events and festivals will offer free hepatitis A and B vaccine, check the

Sexual Transmitted Disease Program's web site in May 2011 at):
http://publichealth.lacounty.gov/std/hepatitis_vaccination.htm

Adult HAV and HBV Vaccine Schedule					
Vaccine	Recommended Doses	Recommended Intervals	% of Adults Protected After:		
			1 st Dose	2 nd Dose	3 rd Dose
Hepatitis B (Engerix-B or Recombivax-HB)	3	0, 1-2, 4-6 months	35-55%	75%	>95%
Hepatitis A (Havrix)	2	0, 4-6 months	95%	100%	
Hepatitis A/B combination (Twinrix)	3	0, 1, 6 months	35-55%	75%	>95%

5.2 Hepatitis B and C Treatment Referral

All patients with positive Hepatitis B surface antigen test and positive confirmatory HBV viral load, and no health insurance, should be referred to the LAC Department of Health Services (DHS) for low- and no-cost medical care for eligible County residents. Medical care will be delivered initially at a DHS Comprehensive Health Center (CHC). The DHS process requires the patient make an initial request for an appointment by calling the CHC site most convenient to where the patient resides [refer to **Appendix M** for a list of locations to access DHS Medical Services and contact information]. The process is lengthy and may require the patient set an appointment several months out from the time they have initially contacted DHS/CHC. The DHS/CHC will evaluate the patient at their first medical appointment and then make the determination whether treatment requires referral to the DHS hepatology clinic at LAC/USC Medical Center or UCLA Harbor Medical Center. Sexual partners of patients testing positive for Hepatitis B surface antigen should be referred for screening and vaccination at their primary healthcare provider, the nPEP clinical site, or the LAC DPH.

Patients with Hepatitis B may also be referred to the Asian Pacific Liver Center (APLC) for additional education and support services. They can be reached at (213) 207-5793. APLC accepts patients without insurance at a reduced fee for service.

An additional resource for treatment options is the patient navigator program. Patient navigators guide patients through the complexities of the health care system, removing barriers to early diagnosis and treatment. Hep B Free LA, an LA based non-profit, can assist a newly diagnosed individual with hepatitis B through the LAC healthcare system. This includes getting appointments and, if needed, applying for financial assistance programs. Contact information for the hepatitis B patient navigation program is Duc Tran and he can be reached at mdtran@ucla.edu

Treatment with Truvada or Combivir in patients with chronic active hepatitis B has been associated with flares of hepatitis upon discontinuation of treatment. Such patients will be referred to appropriate hepatology medical care for close monitoring of liver function during the nPEP course and for the duration of the 6-months of follow-up, and beyond as needed. If there is a gap in the time between referral and appointment for hepatology care, the treating provider at the nPEP program should continue to see the patient and monitor liver function on a monthly basis until such time as the patient can be transitioned into hepatology subspecialty care.

All patients with positive Hepatitis C antibody test and positive confirmatory HCV vrial load, and no insurance, should be referred to the LAC Department of Health Services (DHS) for low- and no-cost health care for eligible County residents. Medical care will be delivered initially at a DHS Comprehensive Health Center (CHC). The DHS process requires the patient make an initial request for an appointment by calling the CHC site most convenient to where the patient resides [refer to **Appendix M** for a list of locations to access DHS Medical Services and contact information]. The process is lengthy and may require the patient set an appointment several months out from the time they have initially contacted DHS/CHC. The DHS/CHC will evaluate the patient at their first medical appointment and then make the determination whether treatment requires referral to the DHS hepatology clinic at LAC/USC Medical Center or UCLA Harbor Medical Center. Patients may also be directed to the Hepatitis C Task Force for LAC, for additional resources, support, and education: www.hepctaskforcela.org.

SECTION 6: PARTNER SERVICES

6.0 Reporting and Partner Services

When an nPEP or *source* patient has a positive result for a reportable STI, the program staff will complete a California STD Confidential Morbidity Report

(CMR), which will be reviewed by the referring physician and submitted to the LAC Department of Public Health, Sexually Transmitted Disease Program, as required by state law [refer to **Appendix J** for CMR for STDs]. Additionally, any nPEP or *source* patients who test positive for HIV, either by ELISA and confirmed western blot, or by HIV viral load testing, should have an HIV CMR completed and sent to the LAC Department of Public Health, HIV Epidemiology Program within 7 days of the diagnosis [refer to **Appendix K** for CMR for HIV].

All nPEP or *source* patients testing positive for an STI or HIV should be immediately referred to the LAC DPH Partner Counseling and Referral Services (PCRS) Unit. PCRS assists HIV positive individuals with notifying sex partners who may have been exposed to HIV, and facilitates free and confidential HIV and STD testing for partners. PCRS may also assist HIV-positive individuals to link to HIV care. The PCRS Unit contact information is:

Primary Contact:
Jolene Yoneoka
Team Leader/Coordinator
(213) 744-3360

Secondary Contact:
Frank Ramirez
PHI Manager
(213) 744-3342

SECTION 7: SUBSTANCE USE AND SEXUAL RISK ASSESSMENTS

Sexual and substance use risk assessments will be administered at Intake, and 4-6 week, 12 week, and 24 week follow-ups. The risk assessment tool is administered as a component of the HIV testing process and will follow all applicable LAC DPH guidelines [refer to the nPEP Intake Evaluation Form, **Appendix A**]. An HIV risk assessment and risk-reduction counseling session should be a minimum of twenty (20) minutes and supports an nPEP patient to identify the specific behaviors that placed them at risk for HIV. The rationale being that findings from the assessment will support the extent and scope of behavioral risk-reduction counseling and referral to more intensive risk-reduction counseling, if necessary, to address the patient's reported risk behavior. [Refer to **section 8** below for information regarding behavioral risk-reduction counseling.]

SECTION 8: BEHAVIORAL RISK-REDUCTION COUNSELING

Behavioral risk-reduction counseling is an integral component of the PEP-LA program, which supports the delivery of a comprehensive set of HIV prevention services. The occurrence of a high-risk exposure to HIV, coupled with seeking nPEP services to attempt averting HIV seroconversion, provides an opportunity to address the patient's risk behaviors since the patient is likely to be highly motivated during these periods to make an effort to change the behaviors that have placed them at high-risk. The program risk-reduction plan comprises two distinct modalities: 1. brief risk-reduction counseling, a standard CDC procedure provided during the rapid HIV testing process, and 2. intensive risk-reduction counseling, a service referral if deemed warranted as an outcome of the counselor's assessment of the patient's reported risk behavior. Intensive risk-reduction services are operationalized by systematic referral and access to a LAC network of HIV-related prevention services [refer to www.hivla.org for a list of health education, mental health and substance abuse services].

The psychology of risk taking behavior is complex, however, it has been noted that changing behaviors is one of the most challenging components of any medical treatment program. Behavioral risk-reduction programming and other behavioral interventions have had mixed results in accomplishing long-term benefit in terms of reduced HIV and STI acquisition. Recent studies have demonstrated incremental benefit of more intensive risk-reduction programming compared to standard counseling for highest-risk participants.

The high rate of concomitant substance use, especially stimulant use, associated with high-risk sexual behavior and the success of novel technologies such as contingency management (CM) combined with cognitive techniques makes facile referral to such services a logical partnership. The need for mental health referral for a variety of mood and personality disorders often parallels the need for substance abuse services, and referral to such services must be similarly seamless and part of a prevention package offered.

Therefore, brief substance use and sexual risk-reduction counseling will be provided at intake, day 14 telephone "check-in," and each follow-up evaluation to emphasize safer sexual practices and will follow LAC DPH guidelines for HIV prevention counseling as adopted by the CDC. The clinical sites will:

- conduct an HIV risk assessment that supports the counselor and an nPEP patient to identify, acknowledge, and understand the details and context of the patient's HIV risk; and
- provide a patient-centered counseling session that engages the patient in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. The patient-centered counseling session should accomplish the following:
 - Improve the patient's self-perception of risk;
 - Support behavior change previously accomplished or attempted by the patient;
 - Negotiate a workable short-term and long-term risk reduction plan based on the patient's perceived ability to change his or her behavior; and
 - Review the nexus between HIV and STD infections and alcohol and drug use.

At the counselor's determination and based on the outcome of the patient's risk assessment and brief risk-reduction counseling session, referral for intensive risk reduction programming will be offered, when indicated, including county-funded interventional services, or services provided on-site, that are all intended to address the high-risk behaviors of the patient. Intensive behavioral risk-reduction and substance use treatment programs within LAC can be found online at www.hivla.org.

SECTION 9: MEDICATION AND TREATMENT ADHERENCE

Adherence counseling is imperative to ensuring the success of the nPEP services. Such counseling addresses not only issues of compliance to dosing regimen and follow-up treatment, but often preemptively manages toxicity, and can be accomplished with trained pharmacy and program staff, such as a nursing case manager.

All patients will receive medication adherence counseling at intake and an informational/education sheet [refer to **Appendix Q** Sample PEP Adherence Handout]. Patients will receive a subsequent medication adherence counseling session during the 2-week telephone "check-in".

Evaluation of medication adherence will occur at the 2-week telephone "check-in" and 4-6 week visits, using a 4-day patient recall. Based on initial evaluation at intake, patients will receive a tailored adherence plan, which may include the

following: regular telephone contact; email reminders/contact; and cell-phone text message reminders/contact all intended to support the patient's adherence to the prophylaxis. The plan will be revisited at the 2-week telephone "check-in" adherence counseling session, and the adjusted plan will be continued through the end of the 28-day treatment course.

The clinical sites will develop plans that support medication and treatment adherence, including effective methods that assist patients adhere to medication dosing and minimize missing their follow-up appointments.

SECTION 10: CLINICAL MANAGEMENT – TOXICITY ISSUES

10.0 Truvada (tenofovir + emtricitabine)

In the event of intolerance, including but not limited to rash, nausea, vomiting, clinical jaundice, or abdominal pain, an "unscheduled visit" should be made in which a directed clinical assessment and laboratory evaluations including creatinine, liver function tests, and complete blood count with differential are performed. Alternative regimens may be substituted, including Combivir (zidovudine + lamivudine).

Dosing of zidovudine + lamivudine (Combivir) is 1 tablet by mouth twice daily. For patients with a creatinine clearance <50 mL/min, including those on hemodialysis, Combivir may be dose-adjusted to 1 tablet by mouth once daily.

10.1 Combivir (zidovudine + lamivudine)

In the event of intolerance, including but not limited to rash, nausea, vomiting, clinical jaundice, abdominal pain, fatigue, dizziness, asthenia, and pallor, an "unscheduled visit" should be made in which a directed clinical assessment and laboratory evaluations including creatinine, liver function tests, and complete blood count with differential are performed.

SECTION 11: PREGNANCY AND BREAST FEEDING

For an exposed patient who is pregnant, consultation with clinical experts is recommended, primarily to assist with toxicity management.

The "standard" regimen should consist of Combivir (zidovudine + lamivudine) dosed as 1 tablet by mouth twice daily.

For an exposed patient who is breast feeding, the patient should be treated as per standard protocol instructions above. The patient should discontinue breast feeding immediately and transition to formula feeding and a pump-and-discard program until the course of nPEP has been completed.

SECTION 12: SEXUAL ASSAULT

Most guidelines recommend offering nPEP services to victims of sexual assault. General advice includes administration of nPEP for receptive vaginal intercourse (RVI), anal intercourse, or a known HIV-positive *source*.

In general, compliance and follow-up in such cases has been poor, and referral to appropriate rape crisis, law enforcement, and mental health services is crucial. STI testing and prophylactic treatment as well as emergency contraception for females of childbearing potential should be offered.

The PEP-LA program will work closely with the LAC Sexual Assault Response Team (SART) Centers to facilitate the delivery of nPEP services to all sexual assault victims when indicated. The SART centers should refer patients they evaluate as eligible for nPEP to the PEP-LA program. These patients will be directly referred to start nPEP at one of the PEP-LA program sites if the 72 hour window can be realized. However, it is preferable that patients receive initial doses or a starter pack at the SART center and then follow up for a complete course of nPEP at the PEP-LA program. The LAC SART center should also be notified when a patient presents to a PEP-LA program site reporting HIV exposure from a sexual assault, if the patient consents. A list of LAC SART Centers and contact information is provided in **Appendix N**.

SECTION 13: MANAGEMENT OF SUSPECTED ACUTE SEROCONVERSION

Signs and symptoms of Acute HIV Infection (AHI) are listed below in **Table 3**. Should a patient present with signs and symptoms consistent with AHI during nPEP treatment, this should trigger immediate referral to HIV specialty care for appropriate work-up, and an HIV viral load should be ordered. Medications should be continued pending return of laboratory tests and expert clinician guidance.

Table 3. Frequency of Symptoms and Findings Associated with Acute HIV-1 Infection

<i>Symptom or Finding</i>	<i>% Patients</i>
Fever	>80–90
Fatigue	>70–90
Rash	>40–80
Headache	32–70
Lymphadenopathy	40–70
Pharyngitis	50–70
Myalgia or arthralgia	50–70
Nausea, vomiting, or diarrhea	30–60
Night sweats	50
Aseptic meningitis	24
Oral ulcers	10–20
Genital ulcers	5–15
Thrombocytopenia	45
Leukopenia	40
Elevated hepatic-enzyme levels	21

SECTION 14: CRITERIA FOR DISCONTINUATION

14.0 Temporary Medication Interruption

Attempts should be made to avoid temporary interruption.

Symptoms should be managed aggressively and proactively in an attempt to avoid discontinuation, provided there is no laboratory evidence of toxicity and the symptoms are mild to moderate. In the event of moderate toxicity with laboratory abnormalities, attempts should be made to transition directly from one regimen to another without interruption. In the event of severe toxicity requiring discontinuation and lack of clarity as to the causative agent, medications should be discontinued and then alternative regimens instituted as soon as clinical and/or biochemical resolution of the toxicity is clearly established. Such decisions will need to be made in conjunction with experts in HIV clinical care.

In the event of inadvertent discontinuation due to missed appointments, loss of medication, or other unforeseen circumstances, treatment should be resumed counting the missed days as part of the 28 day treatment course. It is unlikely that in cases of medication discontinuations > 72 hours that resumption of the course of

treatment will increase efficacy. Treatment should ONLY be reinstituted in the absence of signs/symptoms of AHI [refer to **Table 3**].

14.1 Permanent Medication Discontinuation

Permanent medication discontinuation prior to 28-days of treatment should be limited to patients who are so advised by HIV treatment experts, or have severe toxicity to two or more regimens. In the event of sequential toxicity, consultation with HIV treatment experts should be employed prior to abandonment of treatment efforts.

14.2 Program Discontinuation

Rationale for program discontinuation:

1. Request by the patient to withdraw from the program.
2. Patient, in the judgment of program medical providers, is unable to comply with provisions of the treatment regimen in such a way as to be more likely to result in harm to the patient.
3. HIV-positive ELISA or viral load result at any time point. Such patients will be referred to appropriate private or LAC HIV expert care for follow-up and ongoing evaluation and treatment.

SECTION 15: COMPLETED PATIENT EVALUATION FORMS

Patient evaluation forms are the primary method for collection of program information. Evaluation forms can be found in the Appendix of this manual.

1. nPEP Intake Evaluation Form
2. nPEP 2 Week Telephone Evaluation Form
3. nPEP 4-6, 12, and 24 Week Evaluation Form
4. nPEP Source Information Evaluation Form

The program utilizes Teleform technology to scan and input information collected on these forms uniquely designed for the PEP-LA program. The technology is precise regarding how the “user” is to complete the forms. Please adhere to these instructions when completing program evaluation forms:

- Use black ink when completing the forms.

- Fill-in bubbles (that represent choices) completely. Do not mark the bubbles with a “check-mark” or an “X”.

Shade Circles Like This--> ●

Not Like This-->  

When writing within a text field (either a single character box or fields intended for multiple words):

- Remain within the boundaries of the fields otherwise the scanner will not read the text.
- Use all CAPS, when and where possible (we concede this will be difficult for lengthy text field responses but should be easily accomplished for single character text boxes).
- Only a single character (whether it is a letter or number) should be placed in each text box.

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

- Read the instructions carefully for each question to distinguish between multiple answer choices (choose all that apply) or a single answer choice (choose only one).
- Read any instructions carefully for any skip patterns.
- If you make a mistake or incorrectly marked an answer choice, e.g., marked multiple answer choices when the question only allows for a single answer choice, please start over with a blank form.

How to print your forms from PDF format and photocopying:

- It is preferable to utilize master copies of the forms from the electronic PDF file provided to you from OAPP. To print from the PDF file, go to the “Print” dialogue box and choose “None” under the heading “Page Scaling.” (see Figure below) This will ensure the copy matches the dimensions originally set when creating the form. Note, that if this option is not chosen, the printed copy of the form will be smaller than it should be.
- When making photocopies of the forms, only photocopy from the master printed copy of the PDF. Additionally, ensure that all photocopies are aligned carefully according to the positional gridlines on your photocopy machine.

Other considerations:

- Please do not mark, cover or otherwise obliterate the Form ID number (the top left hand corner of each page of the forms) because the scanner will not recognize which form it is attempting to read.
- Refrain from any unnecessary marks on the forms since the scanner will attempt to read and interpret any all marks on the forms.
- Do not place staples through the cornerstones (black cubes on each corner of the forms) or Form ID numbers.
- Do not use “white out” or correction tape products on the forms.
- Do not print the forms on color paper.

SECTION 16: DATA TRANSFER

There will be no data entry associated with the patient evaluation forms. Each site will be responsible for collecting all completed forms and maintaining a batch file. The batch file of forms is to be delivered to OAPP on a regular and reliable routine, and at least once a month, to ensure appropriate imputation, documentation and reimbursement for services delivered. Additionally, the site is responsible for developing a plan that ensures the batch file of completed forms is stored in a secure and confidential manner for the period of time prior to its delivery to OAPP.

SECTION 17: APPENDICES

Appendix A	nPEP Intake Evaluation Form
Appendix B	nPEP 2 Week Telephone Evaluation Form
Appendix C	nPEP 4-6, 12, and 24 Week Evaluation Form
Appendix D	nPEP Source Information Evaluation Form
Appendix E	Public Health Laboratory Test Request Form – Viral Load
Appendix F	Public Health Laboratory Shipping/Storage Form for Viral Load
Appendix G	Tracking Log for Stored Specimens
Appendix H	Public Health Laboratory Test Request Form – STDs
Appendix I	Instructions for the Self-Collection of a Rectal Swab
Appendix J	Confidential Morbidity Report for STD Reporting
Appendix K	Confidential Morbidity Report for HIV Reporting http://publichealth.lacounty.gov/hiv/hivreporting/LACWorkingAdult_HIV-AIDS_Form_v1_5.pdf
Appendix L	LAC Sites Offering Free or Low Cost Hep A&B Vaccinations http://publichealth.lacounty.gov/std/clinics.htm
Appendix M	DHS Medical Service Location Sites
Appendix N	LAC Sexual Assault Response Team (SART) Centers
Appendix O	Standard Operating Procedure (SOP) for Coordination of Patient Referral between Sites
Appendix P	ARV Medication Codes (for Source Information Evaluation Form)
Appendix Q	Sample PEP Adherence Handout

ADDITIONAL PROVISIONS
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HIV AND STD PROGRAMS
PREVENTION SERVICES
(NON-BUSINESS ASSOCIATE – COVERED ENTITY)

REVISED: 11-21-11

ADDITIONAL PROVISIONS
PREVENTION SERVICES AGREEMENT

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**ADDITIONAL PROVISIONS
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HIV AND STD PROGRAMS (DHSP)**

PREVENTION SERVICES

1. **ADMINISTRATION:** County's Director of Public Health ("DPH") or his/her authorized designee(s) (hereafter collectively "Director") shall have the authority to administer this Agreement on behalf of County. Contractor agrees to extend to Director the right to review and monitor Contractor's programs, policies, procedures, and financial and/or other records, and to inspect its facilities for contractual compliance at any reasonable time.

2. **FORM OF BUSINESS ORGANIZATION AND FISCAL DISCLOSURE AND REAL PROPERTY DISCLOSURE:**

A. **Form of Business Organization:** Contractor shall prepare and submit, to Director upon request, a statement executed by Contractor's duly constituted officers, containing the following information:

- (1) The form of Contractor's business organization, i.e., sole-proprietorship, partnership, or corporation.
- (2) Articles of Incorporation and by-laws.
- (3) A detailed statement indicating whether Contractor is totally or substantially owned by another business organization.
- (4) A detailed statement indicating whether Contractor totally or partially owns any other business organization that will be providing services, supplies, materials, or equipment to Contractor or in any manner does business with Contractor under this Agreement.
- (5) If, during the term of this Agreement, the form of Contractor's business organization changes, or the ownership of Contractor changes, or the Contractor's ownership of other businesses dealing with Contractor under this

Agreement changes, Contractor shall notify Director in writing detailing such changes within thirty (30) calendar days prior to the effective date thereof.

B. Fiscal Disclosure: Contractor shall prepare and submit to Director, within ten (10) calendar days following execution of this Agreement a statement, executed by Contractor's duly constituted officers, containing the following information:

(1) A detailed statement listing all sources of funding to Contractor including private contributions. The statement shall include the nature of the funding, services to be provided, total dollar amount, and period of time of such funding.

(2) If during the term of this Agreement, the source(s) of Contractor's funding changes, Contractor shall promptly notify Director in writing detailing such changes.

C. Real Property Disclosure: If Contractor is renting, leasing, or subleasing, or is planning to rent, lease, or sublease, any real property where persons are to receive services hereunder, Contractor shall prepare and submit to Director, within ten (10) calendar days following execution of this Agreement, an affidavit sworn to and executed by Contractor's duly constituted officers, containing the following information:

(1) The location by street address and city of any such real property.

(2) The fair market value of any such real property as such value is reflected on the most recently issued County Tax Collector's tax bill.

(3) A detailed description of all existing and pending rental agreements, leases, and subleases with respect to any such real property, such description to include: the term (duration) of such rental agreement, lease, or sublease; the amount of monetary consideration to be paid to the lessor or sublessor over the term of the rental agreement, lease or sublease; the type and dollar value of any other consideration to be paid to the lessor or sublessor over

the term of the rental agreement, lease, or sublease; the full names and addresses of all parties who stand in the position of lessor or sublessor; if the lessor or sublessor is a private corporation and its shares are not publicly traded (on a stock exchange or over-the-counter), a listing by full names of all officers, directors, and stockholders thereof; and if the lessor or sublessor is a partnership, a listing by full names of all general and limited partners thereof.

(4) A listing by full names of all Contractor's officers, directors, members of its advisory boards, members of its staff and consultants, who have any family relationships by marriage or blood with a lessor or sublessor referred to in Subparagraph (3) immediately above, or who have any financial interest in such lessor's or sublessor's business, or both. If such lessor or sublessor is a corporation or partnership, such listing shall also include the full names of all Contractor's officers, members of its advisory boards, members of its staff and consultants, who have any family relationship, by marriage or blood, to an officer, director, or stockholder of the corporation, or to any partner of the partnership. In preparing the latter listing, Contractor shall also indicate the name(s) of the officer(s), director(s), stockholder(s), or partner(s), as appropriate, and the family relationship which exists between such person(s) and Contractor's representatives listed.

(5) If a facility of Contractor is rented or leased from a parent organization or individual who is a common owner (as defined by Federal Health Insurance Manual 15, Chapter 10, Paragraph 1002.2), Contractor shall only charge the program for costs of ownership. Costs of ownership shall include depreciation, interest, and applicable taxes.

True and correct copies of all written rental agreements, leases, and subleases with respect to any such real property shall be appended to such affidavit and made a part thereof.

3. **NONDISCRIMINATION IN SERVICES:** Contractor shall not discriminate in the provision of services hereunder because of race, color, religion, national origin, ethnic group identification, ancestry, sex, age, or condition of physical or mental handicap, in accordance with requirements of federal and State laws, or in any manner on the basis of the client's/ patient's sexual orientation. For the purpose of this Paragraph, discrimination in the provision of services may include, but is not limited to, the following: denying any person any service or benefit or the availability of the facility; providing any service or benefit to any person which is not equivalent, or is provided in a non-equivalent manner, or at a non-equivalent time, from that provided to others; subjecting any person to segregation or separate treatment in any manner related to the receipt of any service; restricting any person in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service or benefit; and treating any person differently from others in determining admission, enrollment quota, eligibility, membership, or any other requirements or conditions which persons must meet in order to be provided any service or benefit. Contractor shall take affirmative action to ensure that intended beneficiaries of this Agreement are provided services without regard to race, color, religion, national origin, ethnic group identification, ancestry, sex, age, condition of physical or mental handicap, or sexual orientation.

Facility access for handicapped must comply with the Rehabilitation Act of 1973, Section 504, where federal funds are involved, and the Americans with Disabilities Act. Contractor shall further establish and maintain written procedures under which any person, applying for or receiving services hereunder, may seek resolution from Contractor of a complaint with respect to any alleged discrimination in the provision of services by Contractor's personnel. Such procedures shall also include a provision whereby any such person, who is dissatisfied with

Contractor's resolution of the matter, shall be referred by Contractor to the Director, for the purpose of presenting his or her complaint of alleged discrimination. Such procedures shall also indicate that if such person is not satisfied with County's resolution or decision with respect to the complaint of alleged discrimination, he or she may appeal the matter to the State Department of Health Services' Affirmative Action Division. At the time any person applies for services under this Agreement, he or she shall be advised by Contractor of these procedures. A copy of such nondiscrimination in services policy and procedures, as identified hereinabove, shall be posted by Contractor in a conspicuous place, available and open to the public, in each of Contractor's facilities where services are provided hereunder.

4. NONDISCRIMINATION IN EMPLOYMENT:

A. Contractor certifies and agrees, pursuant to the Americans with Disabilities Act, the Rehabilitation Act of 1973, and all other federal and State laws, as they now exist or may hereafter be amended, that it shall not discriminate against any employee or applicant for employment because of, race, color, religion, national origin, ethnic group identification, ancestry, sex, age, or condition of physical or mental handicap, or sexual orientation. Contractor shall take affirmative action to ensure that qualified applicants are employed, and that employees are treated during employment, without regard to race, color, religion, national origin, ethnic group identification, ancestry, sex, age, condition of physical or mental handicap, or sexual orientation in accordance with requirements of federal and State laws. Such action shall include, but shall not be limited to the following: employment, upgrading, demotion, transfer, recruitment or recruitment advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship. Contractor shall post in conspicuous places in each of Contractor's facilities providing services hereunder, positions available and open to employees and applicants for employment, and notices setting forth the provisions of this Paragraph.

B. Contractor shall, in all solicitations or advertisements for employees placed by or on behalf of Contractor, state that all qualified applicants shall receive consideration for employment without regard to race, color, religion, national origin, ethnic group identification, ancestry, sex, age, condition of physical or mental handicap, or sexual orientation, in accordance with requirements of federal and State laws.

C. Contractor shall send to each labor union or representative of workers with which it has a collective bargaining agreement or other contract of understanding a notice advising the labor union or workers' representative of Contractor's commitments under this Paragraph.

D. Contractor certifies and agrees that it shall deal with its subcontractors, bidders, or vendors without regard to race, color, religion, national origin, ethnic group identification, ancestry, sex, age, condition of physical or mental handicap, or sexual orientation, in accordance with requirements of federal and State laws.

E. Contractor shall allow federal, State, and County representatives, duly authorized by Director, access to its employment records during regular business hours in order to verify compliance with the anti-discrimination provisions of this Paragraph. Contractor shall provide such other information and records as such representatives may require in order to verify compliance with the anti-discrimination provisions of this Paragraph.

F. If County finds that any provisions of this Paragraph have been violated, the same shall constitute a material breach of contract upon which Director may suspend or County may determine to terminate this Agreement. While County reserves the right to determine independently that the anti-discrimination provisions of this Agreement have been violated, in addition, a determination by the California Fair Employment and Housing Commission or the Federal Equal Employment Opportunity Commission that Contractor has violated federal or State anti-discrimination laws shall

constitute a finding by County that Contractor has violated the anti-discrimination provisions of this Agreement.

G. The parties agree that in the event Contractor violates any of the anti-discrimination provisions of this Paragraph, County shall be entitled, at its option, to the sum of Five Hundred Dollars (\$500) pursuant to California Civil Code Section 1671 as liquidated damages in lieu of canceling, terminating, or suspending this Agreement.

5. FAIR LABOR STANDARDS ACT: Contractor shall comply with all applicable provisions of the Federal Fair Labor Standards Act, and shall indemnify, defend, and hold harmless County, its agents, officers, and employees from any and all liability including, but not limited to, wages, overtime pay, liquidated damages, penalties, court costs, and attorneys' fees arising under any wage and hour law including, but not limited to, the Federal Fair Labor Standards Act for services performed by Contractor's employees for which County may be found jointly or solely liable.

6. EMPLOYMENT ELIGIBILITY VERIFICATION: Contractor warrants that it fully complies with all federal statutes and regulations regarding employment of aliens and others, and that all its employees performing services hereunder meet the citizenship or alien status requirements contained in federal statutes and regulations. Contractor shall obtain, from all covered employees performing services hereunder, all verification and other documentation of employment eligibility status required by federal statutes and regulations, as they currently exist and as they may be hereafter amended. Contractor shall retain such documentation for all covered employees for the period prescribed by law. Contractor shall indemnify, defend, and hold harmless County, its officers, and employees from employer sanctions and any other liability which may be assessed against Contractor or County in connection with any alleged violation of federal statutes or regulations pertaining to the eligibility for employment of persons performing services under this Agreement.

7. CONSIDERATION OF HIRING COUNTY EMPLOYEES TARGETED FOR LAYOFF/OR RE-EMPLOYMENT LIST: Should Contractor require additional or replacement personnel after the effective date of this Agreement to perform the services set forth herein, Contractor shall give first consideration for such employment openings to qualified, permanent County employees who are targeted for layoff or qualified, former County employees who are on a re-employment list during the life of this Agreement.

8. CONSIDERATION OF HIRING GAIN/GROW PROGRAM PARTICIPANTS:

A. Should Contractor require additional or replacement personnel after the effective date of this Agreement, Contractor shall give consideration for any such employment openings to participants in the County's Department of Public Social Services Greater Avenues for Independence (GAIN) Program or General Relief Opportunity for Work (GROW) Program who meet Contractor's minimum qualifications for the open position. For this purpose, consideration shall mean that Contractor will interview qualified candidates. County will refer GAIN/GROW participants by job category to Contractor.

B. In the event that both laid-off County employees and GAIN/GROW participants are available for hiring, County employees shall be given first priority.

9. RECORDS AND AUDITS:

A. Service Records: Contractor shall maintain all service records related to this agreement for a minimum period of five (5) years following the expiration or prior termination of this Agreement. Contractor shall provide upon request by County, accurate and complete records of its activities and operations as they relate to the provision of services, hereunder. Records shall be accessible as detailed in the subsequent sub-paragraph.

B. Financial Records: Contractor shall prepare and maintain on a current basis, complete financial records in accordance with generally accepted accounting principles and also in accordance with written guidelines, standards, and procedures

which may from time to time be promulgated by Director. Such records shall clearly reflect the actual cost of the type of service for which payment is claimed and shall include, but not be limited to:

(1) Books of original entry which identifies all designated donations, grants, and other revenues, including County, federal, and State revenues and all costs by type of service.

(2) A General Ledger.

(3) A written cost allocation plan which shall include reports, studies, statistical surveys, and all other information Contractor used to identify and allocate indirect costs among Contractor's various services. Indirect costs shall mean those costs incurred for a common or joint objective which cannot be identified specifically with a particular project or program

(4) Personnel records which show the percentage of time worked providing services claimed under this Agreement. Such records shall be corroborated by payroll timekeeping records, signed by the employee and approved by the employee's supervisor, which show time distribution by programs and the accounting for total work time on a daily basis. This requirement applies to all program personnel, including the person functioning as the executive director of the program, if such executive director provides services claimed under this Agreement.

(5) Personnel records which account for the total work time of personnel identified as indirect costs in the approved contract budget. Such records shall be corroborated by payroll timekeeping records signed by the employee and approved by the employee's supervisor. This requirement applies to all such personnel, including the executive director of the program, if such executive director provides services claimed under this Agreement.

The entries in all of the aforementioned accounting and statistical records must be readily traceable to applicable source documentation (e.g., employee timecards, remittance advice, vendor invoices, appointment logs, client/patient ledgers). The client/patient eligibility determination and fees charged to, and collected from clients/patients must also be reflected therein. All financial records shall be retained by Contractor at a location within Los Angeles County during the term of this Agreement and for a minimum period of five (5) years following expiration or earlier termination of this Agreement, or until federal, State and/or County audit findings are resolved, whichever is later. During such retention period, all such records shall be made available during normal business hours within (10) calendar days, to authorized representatives of federal, State, or County governments for purposes of inspection and audit. In the event records are located outside Los Angeles County and Contractor is unable to move such records to Los Angeles County, then Contractor shall permit such inspection or audit to take place at an agreed to outside location, and Contractor shall pay County for all travel, per diem, and other costs incurred by County for any inspection and audit at such other location. Contractor shall further agree to provide such records, when possible, immediately to County by facsimile/FAX, or through the Internet (i.e., electronic mail ["e-mail"]), upon Director's request. Director's request shall include appropriate County facsimile/FAX number(s) and/or e-mail address(es) for Contractor to provide such records to County. In any event, Contractor shall agree to make available the original documents of such FAX and e-mail records when requested by Director for review as described hereinabove.

C. Preservation of Records: If following termination of this Agreement Contractor's facility is closed or if ownership of Contractor changes, within forty-eight (48) hours thereafter, the Director is to be notified thereof by Contractor in writing and arrangements are to be made by Contractor for preservation of the client/patient and financial records referred to hereinabove.

D. Audit Reports: In the event that an audit of any or all aspects of this Agreement is conducted of Contractor by any federal or State auditor, or by any auditor or accountant employed by Contractor or otherwise, Contractor shall file a copy of each such audit report(s) with the Director and County's Auditor Controller within thirty (30) calendar days of Contractor's receipt thereof, unless otherwise provided for under this Agreement, or under applicable federal or State regulations. To the extent permitted by law, County shall maintain the confidentiality of such audit report(s).

E. Independent Audit: Contractor's financial records shall be audited by an independent auditor for every year that this Agreement is in effect.

The audit shall satisfy the requirement of the Federal Office of Management and Budget (OMB) Circular Number A-133. The audit shall be made by an independent auditor in accordance with Governmental Financial Auditing Standards developed by the Comptroller General of the United States, and any other applicable federal, State, or County statutes, policies, or guidelines. Contractor shall complete and file such audit report(s) with the County's DPH – Department of Public Health – Financial Services Division no later than the earlier of thirty (30) days after receipt of the auditor's report(s) or nine (9) months after the end of the audit period.

If the audit report(s) is not delivered by Contractor to County within the specified time, Director may withhold all payments to Contractor under all service agreements between County and Contractor until such report(s) is delivered to County.

The independent auditor's work papers shall be retained for a minimum of three (3) years from the date of the report, unless the auditor is notified in writing by County to extend the retention period. Audit work papers shall be made available for review by federal, State, or County representatives upon request.

F. Federal Access to Records: If, and to the extent that, Section 1861(v) (1) (I) of the Social Security Act [42 United States Code ("U.S.C.") Section 1395x(v)(1)(I)] is

applicable, Contractor agrees that for a period of five (5) years following the furnishing of services under this Agreement, Contractor shall maintain and make available, upon written request, to the Secretary of the United States Department of Health and Human Services or the Comptroller General of the United States, or to any of their duly authorized representatives, the contracts, books, documents, and records of Contractor which are necessary to verify the nature and extent of the cost of services provided hereunder. Furthermore, if Contractor carries out any of the services provided hereunder through any subcontract with a value or cost of Ten Thousand Dollars (\$10,000) or more over a twelve (12) month period with a related organization (as that term is defined under federal law), Contractor agrees that each such subcontract shall provide for such access to the subcontract, books, documents, and records of the subcontractor.

G. Program and Audit/Compliance Review: In the event County representatives conduct a program review and/or an audit/compliance review of Contractor, Contractor shall fully cooperate with County's representatives. Contractor shall allow County representatives access to all records of services rendered and all financial records and reports pertaining to this Agreement and shall allow photocopies to be made of these documents utilizing Contractor's photocopier, for which County shall reimburse Contractor its customary charge for record copying services, if requested. Director shall provide Contractor with at least ten (10) working days prior written notice of any audit/compliance review, unless otherwise waived by Contractor.

County may conduct a statistical sample audit/compliance review of all claims paid by County during a specified period. The sample shall be determined in accordance with generally accepted auditing standards. An exit conference shall be held following the performance of such audit/ compliance review at which time the

results shall be discussed with Contractor. Contractor shall be provided with a copy of any written evaluation reports.

Contractor shall have the opportunity to review County's findings on Contractor, and Contractor shall have thirty (30) calendar days after receipt of County's audit/compliance review results to provide documentation to County representatives to resolve the audit exceptions. If, at the end of the thirty (30) calendar day period, there remains audit exceptions which have not been resolved to the satisfaction of County's representatives, then the exception rate found in the audit, or sample, shall be applied to the total County payment made to Contractor for all claims paid during the audit/compliance review period to determine Contractor's liability to County.

H. Failure to Comply: Failure of Contractor to comply with the terms of this Paragraph shall constitute a material breach of contract upon which Director may suspend or County may immediately terminate this Agreement.

10. REPORTS: Contractor shall make reports as required by County, or DPH, concerning Contractor's activities and operations as they relate to this Agreement and the provision of services hereunder. In no event, however may County, or DPH, require such reports unless Director has provided Contractor with at least thirty (30) calendar days' prior written notification thereof. Director's notification shall provide Contractor with a written explanation of the procedures for reporting the information required.

11. PUBLIC ANNOUNCEMENTS, LITERATURE: Contractor agrees that all materials, public announcements, literature, audiovisuals, and printed materials utilized in association with this Agreement, shall have prior written approval from the Director or his/her designee prior to its publication, printing, duplication, and implementation with this Agreement. All such materials, public announcements, literature, audiovisuals, and printed material shall include an acknowledgment that funding for such public announcements, literature, audiovisuals, and printed materials was made possible by the County of Los Angeles,

Department of Public Health and other applicable funding sources. Contractor further agrees that all public announcements, literature, audiovisuals, and printed material developed or acquired by Contractor or otherwise, in whole or in part, under this Agreement, and all works based thereon, incorporated therein, or derived there from, shall be the sole property of County.

Contractor hereby assigns and transfers to County in perpetuity for all purposes all Contractors' rights, title, and interest in and to all such items, including, but not limited to, all unrestricted and exclusive copyrights and all renewals and extensions thereof.

With respect to any such items which come into existence after the commencement date of the Agreement, Contractor shall assign and transfer to County in perpetuity for all purposes, without any additional consideration, all Contractor's rights, title, and interest in and to all such items, including, but not limited to, all unrestricted and exclusive copyrights and all renewals and extensions thereof.

For the purposes of this Agreement, all such items shall include, but not be limited to, written materials (e.g., curricula, text for vignettes, text for public service announcements for any and all media types, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar promotional and educational materials using photographs, slides, drawings, or paintings).

12. CONFIDENTIALITY: Contractor agrees to maintain the confidentiality of its records and information including, but not limited to, billings, County records, and client/patient records, in accordance with all applicable federal, State, and local laws, ordinances, rules, regulations, and directives relating to confidentiality. Contractor shall inform all its officers, employees, agents, subcontractors, and others providing services hereunder of said confidentiality provision of this Agreement. Contractor shall indemnify and hold harmless County, its officers, employees, and agents, from and against any and all loss, damage, liability, and expense arising out of any disclosure of such records and information by Contractor, its officers, employees, agents, and subcontractors.

13. CONTRACTOR'S OBLIGATION AS A NON-BUSINESS ASSOCIATE UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) OF 1996:

The parties acknowledge the existence of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). Contractor understands and agrees that, as a provider of medical treatment services, it is a "covered entity" under HIPAA and, as such, has obligations with respect to the confidentiality, privacy and security of patient's medical information, and must take certain steps to preserve the confidentiality of this information, both internally and externally, including the training of its staff and the establishment of proper procedures for the release of such information, and the use of appropriate consents and authorizations specified under HIPAA.

The parties acknowledge their separate and independent obligations with respect to HIPAA, and that such obligations relate to transactions and code sets, privacy, and security. Contractor understands and agrees that it is separately and independently responsible for compliance with HIPAA in all these areas and that County has not undertaken any responsibility for compliance on Contractor's behalf. Contractor has not relied, and will not in any way rely, on County for legal advice or other representations with respect to Contractor's obligations under HIPAA, but will independently seek its own counsel and take the necessary measures to comply with the law and its implementing regulations.

"CONTRACTOR AND COUNTY UNDERSTAND AND AGREE THAT EACH IS INDEPENDENTLY RESPONSIBLE FOR HIPAA COMPLIANCE AND AGREE TO TAKE ALL NECESSARY ACTIONS TO COMPLY WITH THE REQUIREMENTS OF THE HIPAA LAW AND IMPLEMENTING REGULATIONS RELATED TO TRANSACTIONS AND CODE SET, PRIVACY AND SECURITY. EACH PARTY FURTHER AGREES TO INDEMNIFY AND HOLD HARMLESS THE OTHER PARTY (INCLUDING THEIR OFFICERS, EMPLOYEES, AND AGENTS), FOR ITS FAILURE TO COMPLY WITH HIPAA."

14. RESTRICTIONS ON LOBBYING:

A. Federal Certification and Disclosure Requirement: Because federal monies are to be used to pay for Contractor's services under this Agreement, Contractor shall comply with all certification and disclosure requirements prescribed by Section 319, Public Law 101-121 (Title 31, U.S.C., Section 1352) and any implementing regulations, and shall ensure that each of its subcontractors receiving funds provided under this Agreement also fully comply with all such certification and disclosure requirements.

B. County Lobbyists: Contractor and each County lobbyist or County lobbying firm as defined in Los Angeles County Code Section 2.160.010, retained by Contractor, shall fully comply with the County Lobbyist Ordinance, Los Angeles County Code Chapter 2.160. Failure on the part of Contractor or any County lobbyist or County lobbying firm retained by Contractor to fully comply with the County Lobbyist Ordinance shall constitute a material breach of contract upon which Director may suspend or County may immediately terminate this Agreement.

15. UNLAWFUL SOLICITATION: Contractor shall require all of its employees performing services hereunder to acknowledge in writing understanding of and agreement to comply with the provisions of Article 9 of Chapter 4 of Division 3 (commencing with Section 6150) of the Business and Professions Code of the State of California (i.e., State Bar Act provisions regarding unlawful solicitation as a runner or capper for attorneys) and shall take positive and affirmative steps in its performance hereunder to ensure that there is no violation of such provisions by its employees. Contractor shall utilize the attorney referral services of all those bar associations within Los Angeles County that have such a service.

16. LICENSES, PERMITS, REGISTRATIONS, ACCREDITATIONS, CERTIFICATES: Contractor shall obtain and maintain during the term of this Agreement, all appropriate licenses, permits, registrations, accreditations, and certificates required by federal, State, and local law for the operation of its business and for the provision of services hereunder.

Contractor shall ensure that all of its officers, employees, and agents who perform services hereunder obtain and maintain in effect during the term of this Agreement, all licenses, permits, registrations, accreditations, and certificates required by federal, State, and local law which are applicable to their performance hereunder. Contractor shall provide a copy of each license, permit, registration, accreditation, and certificate upon request of County's Department of Public Health (DPH) - at any time during the term of this Agreement.

17. CONFLICT OF INTEREST:

A. No County employee whose position in County enables him/her to influence the award or administration of this Agreement or any competing agreement, and no spouse or economic dependent of such employee, shall be employed in any capacity by Contractor, or have any other direct or indirect financial interest in this Agreement. No officer or employee of Contractor who may financially benefit from the provision of services hereunder shall in any way participate in County's approval, or ongoing evaluation, of such services, or in any way attempt to unlawfully influence County's approval or ongoing evaluation of such services.

B. Contractor shall comply with all conflict of interest laws, ordinances, and regulations now in effect or hereafter to be enacted during the term of this Agreement. Contractor warrants that it is not now aware of any facts which create a conflict of interest. If Contractor hereafter becomes aware of any facts which might reasonably be expected to create a conflict of interest, it shall immediately make full written disclosure of such facts to Director. Full written disclosure shall include, without limitation, identification of all persons implicated and complete description of all relevant circumstances.

18. PURCHASES:

A. Purchase Practices: Contractor shall fully comply with all Federal, State, and County laws, ordinances, rules, regulations, manuals, guidelines, and directives, in

acquiring all furniture, fixtures, equipment, materials, and supplies. Such items shall be acquired at the lowest possible price or cost if funding is provided for such purposes hereunder.

B. Proprietary Interest of County: In accordance with all applicable Federal, State, and County laws, ordinances, rules, regulations, manuals, guidelines, and directives, County shall retain all proprietary interest, except their use during the term of this Agreement, in all furniture, fixtures, equipment, materials, and supplies, purchased or obtained by Contractor using any contract funds designated for such purpose. Upon the expiration or earlier termination of this Agreement, the discontinuance of the business of Contractor, the failure of Contractor to comply with any of the provisions of this Agreement, the bankruptcy of Contractor or its giving an assignment for the benefit of creditors, or the failure of Contractor to satisfy any judgment against it within thirty (30) calendar days of filing, County shall have the right to take immediate possession of all such furniture, removable fixtures, equipment, materials, and supplies, without any claim for reimbursement whatsoever on the part of Contractor. County, in conjunction with Contractor, shall attach identifying labels on all such property indicating the proprietary interest of County.

C. Inventory Records, Controls, and Reports: Contractor shall maintain accurate and complete inventory records and controls for all furniture, fixtures, equipment, materials, and supplies, purchased or obtained using any contract funds designated for such purpose. Within ninety (90) calendar days following the effective date of this Agreement, Contractor shall provide Director with an accurate and complete inventory report of all furniture, fixtures, equipment, materials, and supplies, purchased or obtained using any County funds designated for such purpose.

D. Protection of Property in Contractor's Custody: Contractor shall maintain vigilance and take all reasonable precautions, to protect all furniture, fixtures, equipment,

materials, and supplies, purchased or obtained using any contract funds designated for such purpose, against any damage or loss by fire, burglary, theft, disappearance, vandalism, or misuse. Contractor shall contact Director, for instructions for disposition of any such property which is worn out or unusable.

E. Disposition of Property in Contractor's Custody: Upon the termination of the funding of any program covered by this Agreement, or upon the expiration or earlier termination of this Agreement, or at any other time that County may request, Contractor shall: (1) provide access to and render all necessary assistance for physical removal by Director or his authorized representatives of any or all furniture, fixtures, equipment, materials, and supplies, purchased or obtained using any County funds designated for such purpose, in the same condition as such property was received by Contractor, reasonable wear and tear expected; or (2) at Director's option, deliver any or all items of such property to a location designated by Director. Any disposition, settlement, or adjustment connected with such property shall be in accordance with all applicable Federal, State, and County laws, ordinances, rules, regulations, manuals, guidelines, and directives.

19. RETURN OF COUNTY MATERIALS: At expiration or earlier termination of this Agreement, Contractor shall provide an accounting of any unused or unexpended supplies purchased by Contractor with funds obtained pursuant to this Agreement and shall deliver such supplies to County upon County's request.

20. SERVICE DELIVERY SITE - MAINTENANCE STANDARDS: Contractor shall assure that the locations where services are provided under provisions of this Agreement are operated at all times in accordance with County community standards with regard to property maintenance and repair, graffiti abatement, refuse removal, fire safety, landscaping, and in full compliance with all applicable local laws, ordinances, and regulations relating to the property.

County's periodic monitoring visits to Contractor's facilities shall include a review of compliance with the provisions of this Paragraph.

21. DAMAGE TO COUNTY BUILDINGS, FACILITIES, OR GROUNDS: Contractor shall repair, or cause to be repaired, at its own cost, any damage to County buildings, facilities, or grounds, caused by Contractor or any officer, employee, or agent of Contractor. Such repairs shall be made immediately after.

Contractor has become aware of such damage, but in no event, later than thirty (30) calendar days after the occurrence.

If Contractor fails to make timely repairs, County may make any necessary repairs on its own. All costs incurred by County for such repairs, as determine by Director, shall be repaid by Contractor upon demand.

22. STAFFING AND TRAINING/STAFF DEVELOPMENT: Contractor shall operate continuously throughout the term of this Agreement with at least the minimum number of staff required by County. Such personnel shall be qualified in accordance with standards established by County. In addition, Contractor shall comply with any additional staffing requirements which may be included in the Exhibit(s) attached hereto.

During the term of this Agreement, Contractor shall have available and shall provide upon request to authorized representatives of County, a list of persons by name, title, professional degree, salary, and experience who are providing services hereunder. Contractor also shall indicate on such list which persons are appropriately qualified to perform services hereunder. If an executive director, program director, or supervisorial position becomes vacant during the term of this Agreement, Contractor shall, prior to filling said vacancy, notify County's Director. Contractor shall provide the above set forth required information to County's Director regarding any candidate prior to any appointment. Contractor shall institute and maintain appropriate supervision of all persons providing services pursuant to this Agreement.

Contractor shall institute and maintain a training/staff development program pertaining to those services described in the Exhibit(s) attached hereto. Appropriate training/staff development shall be provided for treatment, administrative, and support personnel. Participation of treatment and support personnel in training/staff development should include in-service activities. Such activities shall be planned and scheduled in advance; and shall be conducted on a continuing basis. Contractor shall develop and institute a plan for an annual evaluation of such training/staff development program.

23. INDEPENDENT CONTRACTOR STATUS:

A. This Agreement is by and between County and Contractor and is not intended, and shall not be construed, to create the relationship of employee, agent, servant, partnership, joint venture, or association, as between County and Contractor. The employees and agents of one party shall not be, or be construed to be, employees or agents of the other party for any purpose whatsoever.

B. Contractor shall be solely liable and responsible for providing to, or on behalf of, its officers and employees all legally required employee benefits. County shall have no liability or responsibility for the payment of any salaries, wages, unemployment benefits, disability benefits, federal, State, and local taxes, or other compensation, benefits, or taxes to, or on behalf of, any personnel provided by Contractor.

C. Contractor understands and agrees that all persons furnishing services to County pursuant to this Agreement are, for purposes of workers' compensation liability, the sole employees of Contractor and not employees of County. Contractor shall bear the sole liability and responsibility for furnishing workers' compensation benefits to any person for injuries arising from or connected with services performed by or on behalf of Contractor pursuant to this Agreement.

24. NO INTENT TO CREATE A THIRD PARTY BENEFICIARY CONTRACT:

Notwithstanding any other provision of this Agreement, the parties do not in any way intend that any person shall acquire any rights as a third party beneficiary under this Agreement.

25. TERMINATION FOR INSOLVENCY, DEFAULT, GRATUITIES, AND/OR IMPROPER CONSIDERATIONS, AND CONVENIENCE:

A. Termination for Insolvency: County may terminate this Agreement immediately for default in the event of the occurrence of any of the following:

(1) Insolvency of Contractor. Contractor shall be deemed to be insolvent if it has ceased to pay its debts at least sixty (60) calendar days in the ordinary course of business or cannot pay its debts as they become due, whether Contractor has committed an act of bankruptcy or not, and whether Contractor is insolvent within the meaning of the federal Bankruptcy Law or not;

(2) The filing of a voluntary or involuntary petition under the federal Bankruptcy Law;

(3) The appointment of a Receiver or Trustee for Contractor;

(4) The execution by Contractor of an assignment for the benefit of creditors.

The rights and remedies of County provided in this Paragraph shall not be exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.

B. Termination For Default: County may, by written notice of default to Contractor, terminate this Agreement immediately in any one of the following circumstances:

(1) If, as determined in the sole judgment of County, Contractor fails to perform any services within the times specified in this Agreement or any extension thereof as County may authorize in writing; or

(2) If, as determined in the sole judgment of County, Contractor fails to perform and/or comply with any of the other provisions of this Agreement, or so fails to make progress as to endanger performance of this Agreement in accordance with its terms, and in either of these two (2) circumstances, does not cure such failure within a period of five (5) calendar days (or such longer period as County may authorize in writing) after receipt of notice from County specifying such failure.

In the event that County terminates this Agreement as provided hereinabove, County may procure, upon such terms and in such manner as County may deem appropriate, services similar to those so terminated, and Contractor shall be liable to County for any reasonable excess costs incurred by County for such similar services.

The rights and remedies of County provided in this Paragraph shall not be exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.

C. Termination For Gratuities and/or Improper Consideration: County may, by written notice to Contractor, immediately terminate Contractor's right to proceed under this Agreement, if it is found that gratuities or consideration in any form, were offered or given by Contractor, either directly or through an intermediary, to any County officer, employee, or agent, with the intent of securing the Agreement or securing favorable treatment with respect to the award, amendment, or extension of the Agreement, or making of any determinations with respect to the Contractor's performance pursuant to the Agreement. In the event of such termination, County shall be entitled to pursue the same remedies against Contractor as it could in the event of default by Contractor.

Contractor shall immediately report any attempt by a County officer, employee, or agent, to solicit such improper gratuity or consideration. The report shall be made either

to the County manager charged with the supervision of the employee or agent, or to the County Auditor-Controller's Employee Fraud Hotline at (800) 544-6861.

(Among other items, such improper gratuities and considerations may take the form of cash, discounts, services, the provision of travel or entertainment, or other tangible gifts.)

D. Termination For Convenience: The performance of services under this Agreement may be terminated, with or without cause, in whole or in part, from time to time when such action is deemed by County to be in its best interest. Termination of services hereunder shall be effected by delivery to Contractor of a thirty (30) calendar day advance Notice of Termination specifying the extent to which performance of services under this Agreement is terminated and the date upon which such termination becomes effective.

After receipt of a Notice of Termination and except as otherwise directed by County, Contractor shall:

- (1) Stop services under this Agreement on the date and to the extent specified in such Notice of Termination; and
- (2) Complete performance of such part of the services as shall not have been terminated by such Notice of Termination.

Further, after receipt of a Notice of Termination, Contractor shall submit to County, in the form and with the certifications as may be prescribed by County, its termination claim and invoice. Such claim and invoice shall be submitted promptly, but not later than sixty (60) calendar days from the effective date of termination. Upon failure of Contractor to submit its termination claim and invoice within the time allowed, County may determine on the basis of information available to County, the amount, if any, due to Contractor in respect to the termination, and such determination shall be

final. After such determination is made, County shall pay Contractor the amount so determined.

Contractor for a period of five (5) years after final settlement under this Agreement, in accordance with Paragraph 10, Records and Audits, herein, retain and make available all its books, documents, records, or other evidence, bearing on the costs and expenses of Contractor under this Agreement in respect to the termination of services hereunder.

26. PROHIBITION AGAINST PERFORMANCE OF SERVICES WHILE UNDER THE INFLUENCE: Contractor shall ensure that no employee or physician performs services while under the influence of any alcoholic beverage, medication, narcotic, or other substance that might impair his/her physical or mental performance.

27. NOTICE OF DELAYS: Except as otherwise provided under this Agreement, when either party has knowledge that any actual or potential situation is delaying or threatens to delay the timely performance of this Agreement, that party shall, within two (2) working days, give notice thereof, including all relevant information with respect thereto, to the other party.

28. AUTHORIZATION WARRANTY: Contractor hereby represents and warrants that the person executing this Agreement for Contractor is an authorized agent who has actual authority to bind Contractor to each and every term, condition, and obligation set forth in this Agreement and that all requirements of Contractor have been fulfilled to provide such actual authority.

29. WAIVER: No waiver of any breach of any provision of this Agreement by County shall constitute a waiver of any other breach of such provision. Failure of County to enforce at any time, or from time to time, any provision of this Agreement shall not be construed as a waiver thereof. The remedies herein reserved shall be cumulative and in addition to any other remedies in law or equity.

30. SEVERABILITY: If any provision of this Agreement or the application thereof to any person or circumstance is held invalid, the remainder of this Agreement and the application of such provision to other persons or circumstances shall not be affected thereby.

31. GOVERNING LAWS AND JURISDICTION AND VENUE: This Agreement shall be construed in accordance with and governed by the laws of the State of California.

Contractor hereby agrees to submit to the jurisdiction of the courts of the State of California. The exclusive venue of any action (other than an appeal or an enforcement of a judgment) brought by Contractor, on Contractor's behalf, or on the behalf of any subcontractor which arises from this Agreement or is concerning or connected with services performed pursuant to this Agreement, shall be deemed to be in the courts of the State of California located in Los Angeles County, California.

32. SOLICITATION OF BIDS OR PROPOSALS: Contractor acknowledges that County, prior to expiration or earlier termination of this Agreement, may exercise its right to invite bids or request proposals for the continued provision of the services delivered or contemplated under this Agreement. County and its DPH shall make the determination to re-solicit bids or request proposals in accordance with applicable County and DPH policies.

Contractor acknowledges that County may enter into a contract for the future provision of services, based upon the bids or proposals received, with a provider or providers other than Contractor. Further, Contractor acknowledges that it obtains no greater right to be selected through any future invitation for bids or request for proposals by virtue of its present status as Contractor.

33. CONTRACTOR PERFORMANCE DURING CIVIL UNREST OR DISASTER: Contractor recognizes that County provides essential services to the residents of the communities they serve, and that these services are of particular importance at the time of a riot, insurrection, civil unrest, natural disaster, or similar event. Notwithstanding any other provision of this Agreement, full performance by Contractor during any riot, insurrection, civil

unrest, natural disaster, or similar event is not excused if such performance remains physically possible. Failure to comply with this requirement shall be considered a material breach by Contractor for which Director may suspend or County may immediately terminate this Agreement.

34. COUNTY'S QUALITY ASSURANCE PLAN: County or its agent will evaluate Contractor's performance under this Agreement on not less than an annual basis. Such evaluation will include assessing Contractor's compliance with all contract terms and performance standards. Contractor deficiencies which County determines are severe or continuing and that may place performance of this Agreement in jeopardy if not corrected will be reported to the Board of Supervisors. The report will include improvement/corrective action measures taken by County and Contractor. If improvement does not occur consistent with the corrective action measures, County may terminate this Agreement or impose other penalties as specified in this Agreement.

35. COUNTY'S CHILD SUPPORT COMPLIANCE PROGRAM:

A. CONTRACTOR'S WARRANTY OF ADHERENCE TO COUNTY'S CHILD SUPPORT COMPLIANCE PROGRAM: Contractor acknowledges that County has established a goal of ensuring that all individuals who benefit financially from County through County contracts are in compliance with their court ordered child, family, and spousal support obligations in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.

As required by County's Child Support Compliance Program (County Code Chapter 2.200) and without limiting Contractor's duty under this Agreement to comply with all applicable provisions of law, Contractor warrants that it is now in compliance and shall during the term of this Agreement maintain compliance with employment and wage reporting requirements as required by the federal Social Security Act (42 U.S.C. section 653a) and California Unemployment Insurance Code section 1088.55, and shall

implement all lawfully served Wage and Earnings Withholding Orders or Child Support Services Department ("CSSD") Notices of Wage and Earnings Assignment for Child, Family, or Spousal Support, pursuant to Code of Civil Procedure section 706.031 and Family Code section 5246(b).

B. FAILURE TO COMPLY WITH COUNTY'S CHILD SUPPORT

COMPLIANCE PROGRAM: Failure of Contractor to maintain compliance with the requirements set forth in the CONTRACTOR'S WARRANTY OF ADHERENCE TO COUNTY'S CHILD SUPPORT COMPLIANCE PROGRAM Paragraph immediately above, shall constitute a default by Contractor under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure to cure such default within ninety (90) calendar days of written notice shall be grounds upon which County may terminate this contract pursuant to the Termination for Default Paragraph of this Agreement and pursue debarment of Contractor, pursuant to County Code Chapter 2.202.

36. CONTRACTOR'S EXCLUSION FROM PARTICIPATION IN A FEDERALLY

FUNDED PROGRAM: Contractor hereby warrants that neither it nor any of its staff members is restricted or excluded from providing services under any health care program funded by the federal government, directly or indirectly, in whole or in part, and that Contractor will notify Director within thirty (30) calendar days in writing of: (1) any event that would require Contractor or a staff member's mandatory exclusion from participation in a federally funded health care program; and (2) any exclusionary action taken by any agency of the federal government against Contractor or one or more staff members barring it or the staff members from participation in a federally funded health care program, whether such bar is direct or indirect, or whether such bar is in whole or in part.

Contractor shall indemnify and hold County harmless against any and all loss or damage County may suffer arising from any federal exclusion of Contractor or its staff members from such participation in a federally funded health care program.

Failure by Contractor to meet the requirements of this Paragraph shall constitute a material breach of contract upon which County may immediately terminate or suspend this Agreement.

37. NOTICE TO EMPLOYEES REGARDING THE FEDERAL EARNED INCOME

CREDIT: Contractor shall notify its employees, and shall require each subcontractor to notify its employees, that they may be eligible for the Federal Earned Income Credit under the federal income tax laws. Such notices shall be provided in accordance with the requirements set forth in Internal Revenue Service Notice 1015.

38. CONTRACTOR RESPONSIBILITY AND DEBARMENT:

A. A responsible contractor is a contractor who has demonstrated the attribute of trustworthiness, as well as quality, fitness, capacity, and experience to satisfactorily perform the contract. It is County's policy to conduct business only with responsible contractors.

B. Contractor is hereby notified that, in accordance with Chapter 2.202 of the County Code, if County acquires information concerning the performance of Contractor under this Agreement, or other contracts, which indicates that Contractor is not responsible, County may or otherwise in addition to other remedies provided under this Agreement, debar Contractor from bidding or proposing on, or being awarded and/or performing work on, County contracts for a specified period of time, which generally will not exceed five (5) years, but may exceed five (5) years or be permanent if warranted by circumstances, and terminate this Agreement and any or all existing contracts Contractor may have with County.

C. County may debar Contractor if County's Board of Supervisors finds, in its discretion, that Contractor has done any of the following: (1) violated any term of this Agreement or other contract with County, or a non-profit corporation created by County, (2) committed any act or omission which negatively reflects on Contractor's quality, fitness, or capacity to perform a contract with County or any public entity, or a non-profit corporation created by County, or engaged in a pattern or practice which negatively reflects on same, (3) committed an act or offense which indicates a lack of business integrity or business honesty, or (4) made or submitted a false claim against County or any other public entity.

D. If there is evidence that Contractor may be subject to debarment, Director will notify Contractor in writing of the evidence which is the basis for the proposed debarment and will advise Contractor of the scheduled date for a debarment hearing before County's Contractor Hearing Board.

E. County's Contractor Hearing Board will conduct a hearing where evidence on proposed debarment is presented. Contractor or Contractor's representative, or both, shall be given an opportunity to submit evidence at that hearing. After the hearing, County's Contractor Hearing Board shall prepare a proposed decision, which shall contain a recommendation regarding whether Contractor should be debarred, and if so, the appropriate length of time of the debarment. Contractor and Director shall be provided an opportunity to object to the proposed decision prior to its presentation to County's Board of Supervisors.

F. After consideration of any objections, or if no objections are submitted, a record of the hearing, the proposed decision, and any other recommendation of County's Contractor Hearing Board shall be presented to County's Board of Supervisors. County's Board of Supervisors shall have the right at its sole discretion to modify, deny,

or adopt the proposed decision and recommendation of County's Contractor Hearing Board.

G. If a Contractor has been debarred for a period longer than five (5) years, that Contractor may after the debarment has been in effect for at least five (5) years, submit a written request for review of the debarment determination to reduce the period of debarment or terminate the debarment. County may, in its discretion, reduce the period of debarment or terminate the debarment if it finds that Contractor has adequately demonstrated one or more of the following: (1) elimination of the grounds for which the debarment was imposed, (2) a bona fide change in ownership or management, (3) material, or (4) any other reason that is in the best interest of County.

H. County's Contractor hearing Board will consider a request for review of a debarment determination only where (1) Contractor has been debarred for a period longer than five (5) years, (2) the debarment has been in effect for at least five (5) years, and (3) the request is in writing, states one or more of the grounds for reduction of the debarment, and includes supporting documentation. Upon receiving as appropriate request, County's Contractor Hearing Board will provide notice of the hearing on the request. At the hearing, County's Contractor Hearing Board shall conduct a hearing where evidence on the proposed reduction of debarment period or termination of debarment is presented. This hearing shall be conducted and the request for review decided by County's Contractor Hearing Board pursuant to the same procedures as for a debarment hearing. County's Contractor Hearing Board's proposed decision shall contain a recommendation on the request to reduce the period of debarment or terminate the debarment. County's Contractor Hearing Board shall present its proposed decision and recommendation to the Board of Supervisors. The Board of Supervisors shall have the right to modify, deny, or adopt the proposed decision and recommendation of the County's Contractor Hearing Board.

I. These terms shall also apply to any subcontractors/ consultants of County contractors.

39. DEFAULTED PROPERTY TAX REDUCTION PROGRAM:

A. Contractor's Warranty of Compliance with County's Defaulted Property Tax Reduction Program: Contractor acknowledges that County has established a goal of ensuring that all individuals and businesses that benefit financially from County through contract are current in paying their property tax obligations (secured and unsecured roll) in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.

Unless Contractor qualifies for an exemption or exclusion, Contractor warrants and certifies that to the best of its knowledge it is now in compliance, and during the term of this agreement will maintain compliance, with Los Angeles County Code Chapter 2.206.

B. Termination for Breach of Warranty to Maintain Compliance with County's Defaulted Property Tax Reduction Program: Failure of Contractor to maintain compliance with the requirements set forth in the "CONTRACTOR'S WARRANTY OF COMPLIANCE WITH COUNTY'S DEFAULTED PROPERTY TAX REDUCTION PROGRAM" paragraph immediately above, shall constitute default under this agreement. Without limiting the rights and remedies available to County under any other provision of this agreement, failure of Contractor to cure such default within ten (10) calendar days of notice shall be grounds upon which County may terminate this agreement and/or pursue debarment of Contractor, pursuant to County Code Chapter 2.206.

40. CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION - LOWER TIER COVERED TRANSACTIONS (45 C.F.R.

PART 76): Contractor hereby acknowledges that the County is prohibited from contracting with

and making sub-awards to parties that are suspended, debarred, ineligible or excluded from securing federally funded contracts. By executing this Agreement, Contractor certifies that neither it, nor any of its owners, officers, partners, directors or principals is currently suspended, debarred, ineligible, or excluded from securing federally funded contracts. Further, by executing this Agreement, Contractor certifies that, to its knowledge, none of its subcontractors, at any tier, or any owner, officer, partner director, or other principal of any subcontractor is currently suspended, debarred, ineligible, or excluded from securing federally funded contracts. Contractor shall immediately notify County in writing, during the term of this Agreement, should it or any of its subcontractors or any principals of either being suspended, debarred, ineligible, or excluded from securing federally funded contracts. Failure of Contractor to comply with this provision shall constitute a material breach of this Agreement upon which the County may immediately terminate or suspend this Agreement.

41. RULES AND REGULATIONS: During the time that Contractor's personnel are at County Facilities such persons shall be subject to the rules and regulations of such County Facility. It is the responsibility of Contractor to acquaint persons who are to provide services hereunder with such rules and regulations. Contractor shall immediately and permanently withdraw any of its personnel from the provision of services hereunder upon receipt of oral or written notice from Director, that (1) such person has violated said rules or regulations, or (2) such person's actions, while on County premises, indicate that such person may do harm to County patients, staff, or other individuals.

42. COVENANT AGAINST CONTINGENT FEES:

A. Contractor warrants that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, except bona fide employees or bona fide established commercial or selling agencies maintained by Contractor for the purpose of securing business.

B. For breach or violation of this warranty, County shall have the right to terminate this Agreement and, in its sole discretion, to deduct from the Agreement price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

43. RECYCLED CONTENT BOND PAPER: Consistent with the Board of Supervisors' policy to reduce the amount of solid waste deposited at County landfills, Contractor agrees to use recycled-content bond paper to the maximum extent possible in connection with services to be performed by Contractor under this Agreement.

44. COMPLIANCE WITH THE COUNTY'S JURY SERVICE PROGRAM: This Contract is subject to the provisions of the County's ordinance entitled Contractor Employee Jury Service ("Jury Service Program") as codified in Sections 2.203.010 through 2.203.090 of the Los Angeles County Code.

A. Unless Contractor has demonstrated to the County's satisfaction either that Contractor is not a "Contractor" as defined under the Jury Service Program (Section 2.203.020 of the County Code) or that Contractor qualifies for an exception to the Jury Service Program (Section 2.203.070 of the County Code), Contractor shall have and adhere to a written policy that provides that its Employees shall receive from the Contractor, on an annual basis, no less than five days of regular pay for actual jury service. The policy may provide that Employees deposit any fees received for such jury service with the Contractor or that the Contractor deduct from the Employee's regular pay the fees received for jury service.

B. For purposes of this Subparagraph, "Contractor" means a person, partnership, corporation or other entity which has a contract with the County or a subcontract with a County Contractor and has received or will receive an aggregate sum of \$50,000 or more in any 12-month period under one or more County contracts or subcontracts. "Employee" means any California resident who is a full-time employee of

Contractor. "Full-time" means 40 hours or more worked per week, or a lesser number of hours if: 1) the lesser number is a recognized industry standard as determined by the County, or (2) Contractor has a long-standing practice that defines the lesser number of hours as full-time. Full-time employees providing short-term, temporary services of 90 days or less within a 12-month period are not considered full-time for purposes of the Jury Service Program. If Contractor uses any subcontractor to perform services for the County under the Contract, the subcontractor shall also be subject to the provisions of this subparagraph. The provisions of this subparagraph shall be inserted into any such subcontract agreement and a copy of the Jury Service Program shall be attached to the agreement.

C. If Contractor is not required to comply with the Jury Service Program when the Contract commences, Contractor shall have a continuing obligation to review the applicability of its "exception status" from the Jury Service Program, and Contractor shall immediately notify County if Contractor at any time either comes within the Jury Service Program's definition of "Contractor" or if Contractor no longer qualifies for an exception to the Jury Service Program. In either event, Contractor shall immediately implement a written policy consistent with the Jury Service Program. The County may also require, at any time during the Contract and at its sole discretion, that Contractor demonstrate to the County's satisfaction that Contractor either continues to remain outside of the Jury Service Program's definition of "Contractor" and/or that Contractor continues to qualify for an exception to the Program.

D. Contractor's violation of this subparagraph of the Contract may constitute a material breach of the Contract. In the event of such material breach, County may, in its sole discretion, terminate the Contract and/or bar Contractor from the award of future County contracts for a period of time consistent with the seriousness of the breach.

45. SAFELY SURRENDERED BABY LAW: Contractor shall notify and provide to each of its officers, employees, and agents, and shall require that each of Contractor's subcontractors providing services under this Agreement also notify and provide to each of its officers, employees, and agents, a fact sheet regarding the Safely Surrendered Baby Law, its implementation in Los Angeles County, and where and how to safely surrender a baby. County's fact sheet is available on the Internet at www.babysafela.org for printing and review purposes. Further, Contractor understands that it is County's policy to encourage Contractor and all of its subcontractors, providing services under this Agreement, if any, to voluntarily post County's "Safely Surrendered Baby Law" poster in a prominent position at their place of business. County's Department of Children and Family Services will supply Contractor with the poster to be used.

46. CONTRACTOR'S CHARITABLE ACTIVITIES COMPLIANCE: The Supervision of Trustees and Fundraisers for Charitable Purposes Act regulates entities receiving or raising charitable contributions. The "Nonprofit Integrity Act of 2004" (SB 1262, Chapter 919) increased Charitable Purposes Act requirements. The County seeks to ensure that all County contractors which receive or raise charitable contributions comply with California law in order to protect the County and its taxpayers. A Contractor which receives or raises charitable contributions without complying with its obligations under California law commits a material breach subjecting it to either contract termination or debarment proceedings or both. (County Code Chapter 2.202).

47. CLIENT/PATIENT ELIGIBILITY: If clients/patients are treated hereunder, client/patient eligibility for County's DHSP services shall be documented by Contractor. Contractor shall also document that all potential sources of payments to cover the costs of services hereunder have been identified and that Contractor or client/patient has attempted to obtain such payments. Contractor shall retain such documentation and allow County access to same in accordance with the RECORDS AND AUDITS Paragraph of this Agreement.

48. CLIENT/PATIENT FEES: Clients/patients treated hereunder shall be charged a fee by Contractor. In charging fees, Contractor shall take into consideration the client's/patient's ability to pay for services received. Contractor shall not withhold services because of the client's/patient's inability to pay for such services. In establishing fees, Contractor shall implement a client/patient fee determination system which has been reviewed and approved by the Director. Contractor shall exercise diligence in the billing and collection of client/patient fees.

49. ANNUAL COST REPORT:

A. For each year, or portion thereof, that this Agreement is in effect, Contractor shall provide to County's DPH - DHSP one (1) original annual cost report within thirty (30) calendar days following the close of the contract period. In addition to the requirements of COMPENSATION, Paragraph such cost report shall be prepared in accordance with generally accepted accounting principles, cost report forms, and instructions provided by County.

B. If this Agreement is terminated prior to the close of the contract period, the annual cost report shall be for that Agreement period which ends on the termination date. One (1) original of such report shall be submitted within thirty (30) calendar days after such termination date to County's DPH - DHSP.

C. The primary objective of the annual cost report shall be to provide County with actual revenue and expenditure data for the contract period that shall serve as the basis for determining final amounts due to/from Contractor.

D. If the Annual Cost Report is not delivered by Contractor to County within the specified time, Director may withhold all payments to Contractor under all service agreements between County and Contractor until such report is delivered to County.

50. KNOX-KEENE HEALTH CARE SERVICES REQUIREMENTS: Contractor shall maintain all applicable books and records regarding services rendered to members of the

County of Los Angeles Community Health Plan ("CHP") for a period of five (5) years from the expiration or earlier termination of this Agreement.

During such period, as well as during the term of this Agreement, Director or, the State Department of Managed Health Care or both, reserve the right to inspect at reasonable times upon demand, Contractor's books and records relating to: (1) the provision of health care services to CHP members; (2) the costs thereof; (3) co-payments received by Contractor from CHP members, if any; and (4) the financial condition of Contractor.

Contractor shall maintain such books and records and provide such information to the Director, and to the State Department of Managed Health Care as may be necessary for compliance with the provisions of the Knox-Keene Health Care Service Plan Act of 1975 (Health and Safety Code Sections 1340, et seq.) and all rules and regulations adopted pursuant thereto.

Upon expiration or earlier termination of this Agreement, County shall be liable for payment of covered services rendered by Contractor to a CHP member, who retains eligibility either under the applicable CHP agreement or by operation of law, and who remains under the care of Contractor at the time of such expiration or earlier termination until the services being rendered to the CHP member by Contractor are completed or County makes reasonable and medically appropriate provisions for the assumption of such services.

51. PUBLIC OFFICIALS/OFFICES: No funds pursuant to this Agreement shall be used to feature in any manner the image or voice of any elected official or candidate for elected office, or directly represent the views of any elected public official or candidate for elected office.

52. RECORD RETENTION: Contractor, for a period of five (5) years after final settlement under this Agreement, shall make available to County, at all reasonable times, all its books, records, documents, or other evidence bearing on the costs and expenses of Contractor under this Agreement in respect to the termination of services hereunder. All such books, records, documents, or other evidence shall be retained by Contractor at a location in Southern California and shall be made available within ten (10) calendar days of prior written notice

during County's normal business hours to representatives of County for purposes of inspection or audit.

53. GRIEVANCE-LINE:

A. Definition: The word grievance is often used to refer to complaints, a problem, or cause for dissatisfaction or unhappiness.

B. Grievance-Line is a telephone line that can be used to provide confidential information and assistance to complainant regarding services-related concerns. The line gives individuals an opportunity to voice their complaint or concern regarding HIV/AIDS. The service can be utilized by calling 1(800) 260-8787, Monday through Friday from 8:00 a.m. to 5:00 p.m. (Pacific Standard Time). All after-hour calls will be referred to voice mail and followed-up on the next business day. This number is not intended to respond to urgent, emergent or crisis-related concerns.

C. Grievance-Line Procedure:

(1) DHSP shall investigate the complaint within thirty (30) days of the receipt. Correspondence shall be sent to the complainant and to the Contractor within ten (10) days of acknowledgment of receipt.

(2) Contractor shall develop, implement and maintain written policies/procedures or protocols describing the process by which clients and/or authorized representative may file a complaint with the Grievance-Line.

(3) The plan shall include but not be limited to when and how new clients as well as current clients and recurring are to be informed and made aware in accessing the Grievance-Line.

(4) The client/patient and/or his/her authorized representative shall receive a copy of the procedure along with the toll free contact number.

(5) If the complainant is a non-DHSP related contract caller the call shall be referred to the appropriate regulatory agency.

The availability and use of this Grievance Line does not preclude a complainant (including AIDS and related conditions) from filing a complaint with the Office for Civil Rights (OCR) in San Francisco, California by calling (415) 437-8310 (voice) or (415) 437-8311 (TDD).